CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

September 16, 2005

BY HAND DELIVERY

Mark B. McClellan, M.D., Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1501-P
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule (70 *Federal Register 42674*), July 25, 2005.

Dear Dr. McClellan:

The California Hospital Association (CHA), on behalf of its nearly 500 member hospitals, health systems and ancillary providers appreciates the opportunity to share our comments and concerns in response to the proposed changes to the outpatient prospective payment system (OPPS). In addition to these comments, we support the comments and recommendations of the American Hospital Association (AHA).

APC Relative Weights
Section 1833(t)(9)(A) of the Social Security Act (the Act) requires review and revision of the relative payment weights for Ambulatory Payment Classifications (APC) at least annually.

The Centers for Medicare & Medicaid Services (CMS) proposes to use the same basic methodology it has used each year beginning with the April 7, 2000, final rule to recalibrate the relative APC weights for services furnished on or after January 1, 2006, and before January 1, 2007. To accomplish this, CMS proposes to use the most recent claims and cost report data for outpatient services. For the proposed rule, this was based on the approximately 127 million final action claims for hospital outpatient department services furnished on or after January 1, 2004, and before January 1, 2005. In addition, CMS plans to base APC median costs on claims for services furnished and processed through June 30, 2004.

As it has in past comment letters, CHA continues to support the agency's use of hospital data, and not data from other sources, to set the payment rates, as this information more accurately reflects the costs hospitals incur in providing outpatient services. However, since the implementation of the OPPS in August 2000, payment rates for specific APCs have fluctuated dramatically. For 2006, the proposed rates continue to show significant volatility. There are several reasons for these changes.

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Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Healthcare Association of San Diego and Imperial Counties

First, in the proposed rule, CMS uses the most recent claims data for outpatient services to set 2006 weights or rates, using approximately 49 million whole claims for hospital outpatient department services furnished during calendar year 2004 to create 81 million single records. CHA continues to support the use of the most recent claims and cost report data to set the 2006 payment weights and rates.

Second, CMS continues its efforts to include more claims data in the calculation of the APC payment rates, especially those "multiple procedure claims" that contain charges for more than one service or procedure. CMS is proposing to expand the number of Healthcare Common Procedure Coding System (HCPCS) codes it bypasses on a claim — from 383 in 2005 to 404 in 2006 — for the purposes of creating "pseudo" single-procedure claims. This list of bypassed codes was developed using an empirical approach established in 2005 and described in the rule. CMS also proposes to continue using "date of service matching" — in which charges are attributed to separately payable HCPCS codes based on the code's date of service — as a tool for creation of "pseudo" single claims. In general, we continue to support the use of multi-procedure claims, as we believe that these data improve hospital cost estimates. CHA supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures.

As it did in recalibrating the calendar year (CY) 2005 APC relative payment weights, CMS proposes to continue using "date of service matching" as a tool for creation of "pseudo" single claims. In general, CHA continues to support the expanded list of codes for bypass and the use of "date of service matching."

Finally, as we commented in response to the CY 2005 proposed rule, CHA again urges CMS to provide additional information on the impact of each of the proposed policy changes independently and in combination. To accomplish this, we recommend that CMS provide a public use file that shows the impact of each individual proposed change in methodology so health care providers can review these impacts to determine how they would affect their own operations, and provide a basis for submitting thoughtful comments to CMS.

In addition, although CHA understands the empirical criteria used to determine the additional codes to add to the bypass list, we find it puzzling that the bypass list includes some office visit and consultation services codes but not all of them. For instance, the list includes HCPCS codes 99213 and 99214, but not 99211, 99212, and 99215. One could speculate that this might be explained, in part, by the continuing lack of consistency across hospitals in the use of the evaluation and management (E/M) codes due to the absence of uniform guidelines for hospital coding of E/M services. CHA seeks clarification regarding why only some of the office visit and consultation service E/M codes are included in the bypass list.

Proposed Changes to Packaged Services

CHA commends CMS and the APC Panel's Packaging Subcommittee for initiating a process to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. Currently, when hospitals provide services described by these "N" status codes alone, there is no way to be reimbursed for the costs of providing these services. CHA strongly encourages CMS to continue working

with the APC Panel's Packaging Subcommittee in order to conduct further review of "N" status codes for the purpose of identifying those that should be separately payable.

Expiring Hold Harmless Provision for Transitional Corridor Payments for Certain Rural Hospitals

CHA is concerned about the impact the expiration of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care for populations in their communities.

Rural Hospital Adjustment

In the proposed rule, CMS discusses the study it conducted, in compliance with Section 411 of the Medicare Modernization Act (MMA), to determine if rural hospital outpatient costs exceed urban hospital outpatient costs. As part of this discussion, CMS noted that it conducted an explanatory regression analysis that included three specific classes of rural hospitals — rural sole community hospitals (SCHs), rural hospitals with less than 100 beds that are not rural SCHs, and other rural hospitals. CMS conducted this analysis in order to determine whether the small difference in costs that it found between rural versus urban hospitals in its initial regression analysis was uniform across rural hospitals or whether all of the variation was attributable to a specific class of rural hospitals. The results of this explanatory regression analysis led CMS to its conclusion that rural SCHs are more costly than urban hospitals and, therefore, CMS proposes to provide for a 6.6 percent payment increase for rural SCHs for 2006.

CHA is concerned that Table 6 in the proposed rule, which includes the results of this analysis, does not separately set out the regression results for rural hospitals with 100 or fewer beds that are not rural SCHs. While CMS implies in the preamble text that the results for this category of hospitals were not significant, we believe that it is important to report the results for these hospitals, as they will be the facilities that will be losing their hold-harmless protection in 2006. Therefore, we urge that, in the final rule, CMS either present in Table 6 the regression results for rural hospitals with 100 or fewer beds that are not SCHs or explain why they cannot report these results.

Finally, we are seeking clarification on the following issues:

(1) Would a SCH located in a rural area, which has been reclassified for wage index purposes into an urban area, be eligible for the SCH adjustment?

(2) Would a SCH located in an urban area, which has been reclassified for wage index purposes into a rural area, be eligible for the SCH adjustment?

(3) Would rural SCHs participating in the Rural Community Hospital (RCH) demonstration program be eligible for this adjustment?

Outlier Payments

Outlier payments are additional payments to the APC amount to mitigate some of hospitals' losses when treating high-cost cases. For 2006, CMS proposes to set the target for aggregate outlier payments at 1.0 percent of aggregate total payments under OPPS. Further, to ensure that

estimated 2006 outlier payments would equal one percent of total outpatient PPS payments, CMS proposes to increase the fixed-dollar threshold to $1,575, $400 more than in 2005. Therefore, the cost of a service would have to be both more than 1.75 times the APC payment rate and at least $1,575 more than the APC rate. When the cost of a hospital outpatient service exceeds these thresholds, the outlier payment would be 50 percent of the amount by which the cost of the service exceeds 1.75 times the APC payment rate. CHA seeks further clarification regarding how CMS calculated the proposed fixed-dollar threshold.

While CHA supports the continued need for an outlier policy in all prospective payment systems, including the OPPS, we are concerned about whether CMS has appropriately set the thresholds for outliers in this rule. With the significant changes to outlier policies proposed for 2006, CHA is concerned that Medicare may not actually spend the outlier target set-aside. Therefore, CHA strongly recommends that in the final rule, CMS publish data on actual outlier payments made in 2005 and in prior years, and to continue to report this data in the future.

New Technology

CHA supports CMS' proposal to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel before CMS accepts a New Technology APC application for review.

As we have previously noted in comment letters and verbally before the APC Advisory Panel, the proliferation of G codes and C codes with potentially overlapping descriptions with CPT codes is confusing and burdensome for hospital coders. This confusion has often resulted in incorrect coding and unreliable data available for rate setting. Requiring that an application for a new CPT code be submitted at the time of a New Technology APC application will minimize the need for expedited issuance of temporary G or C codes. HCPCS level II G and C codes are generally not accepted by payers other than Medicare, thus requiring hospitals to have two different codes to report the same procedure depending on the payer. This new process will reduce the duplication of codes so that it will start the process right via CPT rather than starting with a New Technology assignment without a way to report the procedure. While we understand that there may still be circumstances when a G or C code will still be required, having a CPT code available for new technology will simplify the billing and coding process for hospitals because then they will be using one set of codes (i.e., CPT) for all payers as much as possible.

Device manufacturers may not be planning ahead and applying for CPT codes for a variety of reasons, including fear of application denial. In any event, the CPT process involves a more rigorous process than level II HCPCS codes and includes the opportunity for input from the physician specialty societies. Without support from the physician specialties that would embrace the new technology, it is doubtful that the new technology will achieve acceptance from the medical community. Input from the physician community also ensures that the code descriptor selected for new technology procedures will be as close as possible to the terminology that physicians will use to document these services. This in turn will reduce the confusion in determining proper code selection.

Hyperbaric Oxygen
CHA supports CMS' decision to no longer use the respiratory therapy cost-to-charge ratio (CCR) for purposes of calculating the median cost for hyperbaric oxygen therapy (HBOT) and instead use the hospital's overall CCR. However, as some hospitals currently report their costs for HBOT in a separate HBOT line on their cost report, CHA recommends that for 2006, CMS calculate the median rate for HBOT using the HBOT CCR for hospitals that have such separate reporting, and use the overall hospital CCR otherwise. In order to develop more accurate rates for HBOT in the future, CMS should encourage hospitals to report their HBOT costs on a separate HBOT line on their cost report. This should not be administratively difficult for hospitals because HBOT revenues are already captured in a specific separate revenue code, so this would involve only a change in where costs for HBOT are reported on the cost report.

Non-Pass-Throughs
The MMA requires that in 2006, payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to any adjustment for overhead costs. In the proposed rule, CMS evaluates three alternatives for setting 2006 payment rates for these drugs: (1) average and median purchase price data for drugs purchased from July 1, 2003, to June 30, 2004, derived from a General Accountability Office survey of 1,157 hospitals; (2) the average sales price (ASP) data from the fourth quarter of 2004; and (3) mean and median costs derived from the 2004 hospital claims data. After considering the merits and weaknesses of each approach, CMS proposes to pay ASP+6 percent for separately payable drugs and biologicals in 2006.

CHA supports this proposal and agrees that paying for drugs at ASP+6 percent appears to be the best estimate of average acquisition cost available at this time. This also has the additional benefit of providing for consistent payment rates across the hospital OPPS and the physician fee schedule payment systems. Finally, given the inflation in drug prices over time, we believe that the ability to update ASP rates on a quarterly basis is also a key advantage of this proposal. It is important, however, to point out that the proposal to pay at ASP+6 percent will result in significant reductions in payments for some separately payable drugs and biologicals. We are concerned that steep drops in payments for certain drugs and biologicals could have implications on manufacturer production levels of these drugs and could adversely affect patient access to some drug therapies. Therefore, CHA supports the APC Panel's recommendation that CMS carefully track the drug codes to be paid at ASP+6 percent, with a particular focus on drugs with rates that would fall significantly in 2006.

Pharmacy Overhead and Drug Handling Payment Rate Adjustment
In consideration of the Medicare Payment Advisory Commission (MedPAC) recommendations on adjusting the APC rates for separately payable drugs to take into account pharmacy overhead and drug handling costs, CMS proposes:

- To establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biological; and
- To instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with each administration of each separately payable drug and biological based on the code description that best reflects the service the hospital provides to prepare the product for administration to a patient.

Absent the availability of separate hospital charge data on pharmacy overhead, CMS proposes to pay for these costs based on 2 percent of the ASP in 2006. This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP+8 percent, which is a rate that CMS states is equivalent, on average, to the mean cost for drugs derived from hospital claims data.

CHA agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. CHA is concerned, however, that the ASP + 2 percent adjustment for drug handling is not adequate for certain drugs that have very high handling costs due to special equipment or procedures related to the drugs toxicity, special compounding or preparation requirements. As note above, we recommend that in 2006, CMS consider freezing payments for those drugs whose payments would decline significantly from the 2005 rates, particularly for drugs that may have especially complex and costly handling requirements. In the future CMS should work with hospital and pharmacy stakeholders to develop an approach to establish differential add-on payments for drug handling costs to account for a wide variety of drug handling categories.

CHA is strongly opposed to CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals, and to utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome for hospitals to operationalize.

There are many complex issues and administratively burdensome aspects to adopting CMS' proposal for charging for drug handling through the use of these new C-codes. Among these issues are the following:

- Hospitals will have to evaluate the normal mark-up formula for all pharmacy items and pull out the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for separately payable drugs under Medicare while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug.
- For each separately payable drug, hospitals will need to assign the handling charge to one of CMS' proposed new drug handling C-codes. These C-codes are only recognized by and acceptable to Medicare, but not to other payers. Hospitals will therefore have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims, but bill them as a single line item for other payers.
- There is confusion about how the handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient.
- Drug pricing is generated via a pharmacy charging system that is often outside the hospital's normal charging system and may not be able to accommodate the CMS proposed C-codes.
- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, there are questions about how CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

If CMS decides to proceed with implementing this burdensome drug handling C-codes policy, then CHA strongly suggests that CMS provide for a grace period of no less than 90 days after implementation of the 2006 OPPS (April 1, 2006) to allow hospitals to make system changes and educate pharmacy staff, hospital finance staff and coders on the required use of the drug handling C-codes.

Drug Administration

CHA continues to support CMS' proposal to use CPT codes to bill for drug administration services provided in the hospital outpatient department. Using CPT codes simplifies the administrative burden for the coding of drug administration since hospitals can use the same codes for Medicare and non-Medicare payers. We understand that under the proposed methodology, payment for services within the same APC would be collapsed by the Outpatient Code Editor (OCE) into a single per-visit APC payment, as it currently does, until 2005 claims data becomes available, and CMS is able to provide further refinement and recognize resources associated with drug administrations lasting several hours.

Because of the significant changes expected with the new 2006 CPT codes for drug administration, hospitals will need instruction and clarification on the application of these new codes. For example, clarification will be needed regarding the following:

- How the code application may be similar or different for the hospital outpatient department as compared to the physician setting — especially with regards to non-oncology providers o
- Definitions of what constitutes an "initial" vs. subsequent infusion vs. concurrent infusion. infusion and injection services since they often cross departments.
- Definition of "hydration" and how is it different from a hydration that is given for therapeu reasons. In other words, a therapeutic infusion can be hydration.
- How should infusions or titrations be reported? Many times they are established with a documented start time and are administered via pump. As such, many infusions are mai tained by equipment function rather than manual intervention. In these cases, a nurse m aware of the start time of an infusion and may document it; however, it is unlikely that stop time will be documented as:
  - Many bags and many drugs may be hung, one after another.
  - Many infusions are being performed at one time.
  - Orders for drugs may change frequently.
  - Discontinuation of an IV may frequently be documented, but this does not constitute a "stop" of therapy; another line may be started.
  - CMS Transmittals 404, 557 and 566 rescinded, and 573 update with additi changes has led to confusion on how to administrate these processes.

Evaluation and Management Services

Since implementation of the OPPS, hospitals have coded outpatient clinic and eme partment (ED) visits using the same CPT codes as physicians. CHA is again disap CMS has not proposed a national, uniform E/M coding system for outpatient clin its.

This continued lack of uniformity not only puts hospitals at risk for upcoding, but also adversely impacts the ability of CMS to gather consistent, meaningful data on services provided in the ED and hospital clinics. A lack of uniform hospital E/M guidelines still puts hospitals at risk of violating HIPAA standards because hospitals use CPT codes (and the corresponding hospital-specific crosswalk) to report these services to non-Medicare payers.

CHA supports the coding guidelines developed by a panel of experts convened by AHA and the American Health Information Management Association, and urges CMS to propose coding guidelines without delay. Specifically, the panel recommended that CMS:

1. Make payment for ED and clinic visits based on four levels of care.
2. Create HCPCS codes to describe these levels of care as follows:
   - Gxxx1 - Level 1 Emergency Visit
   - Gxxx2 - Level 2 Emergency Visit
   - Gxxx3 - Level 3 Emergency Visit
   - Gxxx4 - Critical Care provided in the Emergency Department
   - Gxxx5 - Level 1 Clinic Visit
   - Gxxx6 - Level 2 Clinic Visit
   - Gxxx7 - Level 3 Clinic Visit
   - Gxxx8 - Critical Care provided in the Clinic
3. Replace all the HCPCS currently in APCs 600, 601, 602, 610, 611, 612 and 620 with GXXX1 through GXXX8.
4. Crosswalk payments from GXXX1 to APC 610, GXXX2 to APC 611, etc.

In the 2004 and 2005 rules, CMS stated it was considering proposed national coding guidelines recommended by the panel, and planned to make any proposed guidelines available on the OPPS website for public comment. CMS also proposed to implement new E/M codes only when it is also able to implement guidelines for their use. This guidance would be issued after ample opportunity for public comment, systems change and provider education. We believe that the E/M coding recommendations made by the independent panel will adequately meet hospitals' needs.

Blood and Blood Products

CMS proposes to continue to make separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific CCR to convert charges to costs for blood and blood products. For blood and blood products with 2006 simulated medians that would experience a decrease of more than 10 percent in comparison to their 2005 payment medians, CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition cost for blood, most notably for leukocyte-reduced red blood cells, and, with the

introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, CHA recommends that CMS set 2006 rates at the greater of: (1) the simulated medians calculated using the 2004 claims data; or (2) the 2005 APC payment medians for these products.

CHA also commends CMS for issuing the comprehensive and clear billing guidelines for blood and blood products in March 2005, addressing issues such as the blood deductible and differences between donor and non-donor states. This document was well-received by hospitals and we believe that it will help to clear up much of the confusion regarding the correct way to code and bill for blood and blood products. CHA will continue to work with and educate our member hospitals, using CMS's blood billing guidelines, regarding appropriate blood coding and billing practices.

Observation Services

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain and asthma. In order to reduce administrative burden on hospitals when attempting to differentiate between packaged and separately payable observation services, CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263 and G0264) and instead create two new HCPCS codes to be used by hospitals to report all observation services: GXXXX (hospital observation services, per hour) and GYYYY (direct admission of patient for hospital observation care). CMS would shift determination of whether or not observation services are separately payable under APC 0339 from the hospital billing department to the OPPS claims processing logic contained in the OCE system.

CHA is pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic. CHA supports the concept of allowing the OCE logic to determine whether services are separately payable as this will result in a simpler and less burdensome process for ensuring payment for the provision of covered outpatient observation services.

We believe, however, that the OCE logic could be used even more efficiently so as to make the HCPCS code GYYYY (Direct admission of patient for hospital observation care) unnecessary. f the hospital bills the GXXXX code and the claim does not include a 45X (emergency depart- ent) or 516 (urgent care center) revenue code, then OCE logic should determine that this was a rect admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 venue code, then it is clear that the patient came in through ED or urgent care center. Once h logic is programmed into the OCE, it would be up to the system to determine whether the ervation is a result of a direct admission or not and pay accordingly.

lly, with respect to the following statement, "That is, hospitals would bill GXXXX when rvation services are provided to any patient admitted to 'observation status,' regardless of tient's status as an *inpatient* [emphasis added] or outpatient." CHA requests that CMS le clarification regarding the reference to inpatient status in the statement. We are con- about this statement because if a patient is admitted as an inpatient, the hospital would not

report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the HIPAA code set standard for reporting procedures for hospital inpatient reporting.

Inpatient Procedures

CMS proposes to remove 25 codes from the "inpatient only" list — a list that identifies services that are unable to receive payment if they are performed in an outpatient setting and assign them to clinically appropriate APCs. CHA continues to urge CMS to eliminate the "inpatient only" list. Physicians, not hospitals, determine where procedures can be safely performed, as well as whether a patient's condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, under current rules, the hospital is penalized if that procedure happens to be on the "inpatient only" list.

If the "inpatient only" list is not eliminated for 2006, CMS should consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the "inpatient only" list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to safely be sent home without an inpatient admission.

Physician Oversight of Nonphysician Practitioners

CHA supports CMS' proposal to defer to state law regarding the need for physicians to review and sign the medical records for outpatients cared for by nonphysician practitioners in critical access hospitals (CAHs). However, we would also recommend that CMS extend the application of this policy to apply to physician review of inpatient records for patients cared for by nonphysician practitioners. If state law permits these practitioners to practice independently, CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that state laws providing independent practice authority generate sufficient control and oversight of these nonphysician practitioners, and we do not believe that quality of care is reduced by nonphysician practitioners

CHA also supports the additional flexibility CMS adds under this proposed policy for states that do not allow for independent practice of nonphysician practitioners — in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.

Ancillary Outpatient Services

In the proposed rule, CMS expresses concern about the increase in the volume of hospital claims that are billed with the –CA modifier from 2003-2004, growing from 18 to 300 claims over that one-year period. This modifier was initially used in 2003 to address situations where a procedure on the "inpatient only" list must be performed to resuscitate or stabilize a patient in a hospital outpatient department with an emergency, life-threatening condition and the patient dies before being admitted as an inpatient. In addition, CMS states that a clinical review of the claims reported using this modifier supports their concerns regarding the increased modifier volume and hospitals' possible incorrect use of the modifier for services that do not meet the payment conditions CMS established.

CHA agrees that the –CA modifier should be used only in unusual and rare circumstances. It is unclear why CMS has seen such a substantial increase in the use of the –CA modifier. The increased volume may be a result of this being a relatively new modifier and hospitals were only beginning to become aware of it. Because of the newness of the code and lack of experience in its application, it could be that hospitals are using the modifier incorrectly. We believe that the –CA modifier policy supports an important function for hospitals that should be preserved. In addition to supporting CMS' efforts to continue to closely monitor hospital use of this modifier, CHA would support any effort to provide additional education on the appropriate use of the –CA modifier.

Partial Hospitalization

CHA is concerned that the 15 percent reduction in the per-diem payment rate for partial hospitalization services that CMS proposes for 2006 could have serious negative consequences for the financial viability of partial hospitalization services in hospitals and health care systems, and could endanger Medicare beneficiary access to these critical services. These services are already quite vulnerable, with many programs closing or limiting the numbers of patients they can accept in recent years.

While CHA recognizes that CMS' proposal was made in order to avoid an even more significant reduction in the payment rate for these services, we do not believe that hospitals that offer partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services. Instead, in the final rule for 2006, CHA recommends that CMS freeze payment rates for partial hospitalization services at the 2005 levels. This approach will provide for payment stability for these services and protect beneficiary access, while allowing CMS adequate time to address the instability in the CMHC data.

Multiple Diagnostic Imaging Procedures

In accordance with a recommendation from MedPAC, CMS proposes to make full payment for the highest paid imaging service and pay 50 percent of the APC payment rate for every additional procedure within the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by contiguous body area.

Absent better justification and more substantial, hospital-based data to support this proposed policy, CHA opposes moving forward with this policy. In developing this policy, CMS relied on Medicare physician fee schedule practice expense data for determining the level of the discount. The agency did not, however, examine hospital cost data. As such, CMS has not presented any evidence to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies, if they exist.

Furthermore, CMS uses different methods to set payments in physician offices and hospital outpatient departments. The physician fee schedule amounts are based on expert opinion of the resources required to perform different services, while the outpatient rates are set based on hospital cost data. Hospital cost data may already reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures. In addition, hospitals conduct

imaging procedures in unique circumstances not found in physician offices, such as in emergency rooms and urgent-care circumstances. We urge CMS to conduct analyses using hospital data before implementing this policy.

In addition to the marked lack of detail provided in the proposed rule, CHA is also concerned with how this policy will be implemented. For example, what exactly is meant by "the same session?" During a suite of tests or an emergency stay, a patient may have an imaging procedure done in the morning, followed by medical review or other tests that indicate the need for a procedure from the same "family" later in the day. In this case, the tests would not be performed at the same time, or even perhaps in the same part of the hospital, and would be incorrectly subject to the discount. The APC advisory panel discussed use of modifier 59 (separate procedure) for this purpose, but rejected it as too burdensome because it would require hospitals to track patients through the course of a day. Regardless of modifier use, this policy would increase the burden on hospitals because they would need to maintain two sets of charges, both with and without the discount.

Finally, the proposed rule states that this policy will be budget neutral. However, no detail is provided on how the impact of the multiple imaging procedures discount was estimated or how the budget neutrality factor was adjusted to account for this. What share of imaging procedures did CMS estimate to be multiple imaging procedures? How were they defined? Will CMS analyze the data later to see if the estimates were correct?

In conclusion, CHA agrees with the APC advisory panel recommendation that this policy should not be implemented without additional analysis and better substantiation.

Interrupted Procedures

CMS proposes to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, there was no indication in the proposed rule that CMS conducted any analysis to support the proposed reduction.

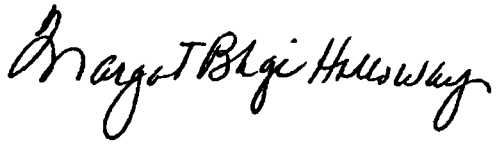
These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted for clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs may actually increase, not decrease, as the team addresses the patient's needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, many of the hospital's costs will have already been incurred. For example, the operating room will have been occupied during the start of the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and will either be disposed of or be reprocessed at additional cost.

CHA believes that there should be no change in payment at this point in time until CMS provides further cost analysis regarding the procedures to which modifiers 52 or 74 are applied in order to evaluate the type of services delivered and the resources expended or not expended in their delivery. CHA believe that before CMS establishes reductions in payments for procedures billed

using these modifiers, there must be evidence supporting the need for payment reductions and the level of reductions that would be applied.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions, please contact me at (202) 488-4688 or mholloway@calhealth.org.

Sincerely,



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September 14, 2005

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Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

File Code: CMS - 1505 - P
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

Dear Dr. McClellen:

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I request that the proposed 2006 Medicare hospital outpatient reimbursement for Apligraf and Dermagraft be corrected in the final rule that will be issued later this year

Thank you for your prompt attention and correction of this 2006 payment issue.

Best regards,

Joe Kiefer DPM

cc: Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

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Sharon K. Davis, MD, FACS
General Surgery
14 W. Jordan Street, Suite C
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16 PM 2:28

SCOD A-D

September 14, 2005

Mark B. McClellen, M.D., PhD
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Attn: CMS - 1505 - P
P. O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

File Code: CMS - 1505 - P
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Best regards,

Sharon K. Davis, MD
SKD/cah

cc: Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

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16 PM 2:29

SCOD -A-D

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8550 University Parkway, Pensacola, FL. 32514
850 969-7990

September 14, 2005

Mark B. McClellen, M.D., PhD
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Attn: CMS - 1505 - P
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chronic wounds. Many of these patients would have had to undergo amputations without the benefits of Dermagraft and Apligraf. As you may be Aware, both the immediate and seven (7) year cost of amputation of a lower Limb is prohibitive. In addition the emotional effect on the patient can be Debilitating. We cannot accurately assess the cost beyond this period as Mortality rate for amputees exceeds 50% by year seven (7).

I, as well as numerous collegues, have been able to use these living tissue substitutes to successfully treat Medicare beneficiaries when other treatment modalities have been unable to heal these difficult wounds.

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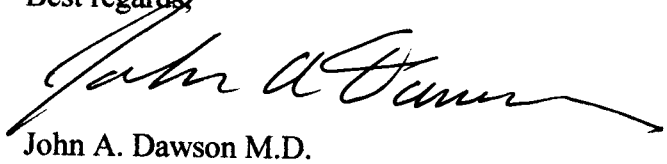

John A. Dawson M.D.
Director

cc: Herb Kuhn
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September 14, 2005

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ic & Sports Medicine Specialists

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EBF/sjt

cc: Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

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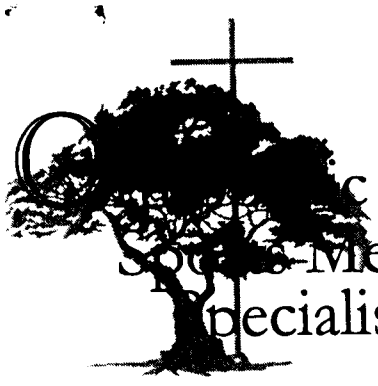

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BY HAND DELIVERY

September 16, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: PROPOSED CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2006 PAYMENT RATES [CMS-1501-P]

Dear Dr. McClellan:

On behalf of the leading not- for-profit hospitals and health systems allied in Premier, I appreciate this opportunity to submit comments on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule ("rule") on the Medicare Hospital Outpatient Prospective Payment System ("HOPPS") for CY 2006, as published in the July 25, 2005 *Federal Register*.

Premier is a strategic alliance of approximately 200 independent, not-for-profit health systems that operate or are affiliated with more than 1,400 hospitals and healthcare sites nationwide. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the effective operation of the HOPPS and IPPS, as we strive provide optimal patient care.

Premier's principal recommendations and/or concerns are summarized below and discussed in the body of this letter.

There are significant changes in reimbursement levels proposed for prescription drugs in the recent notice, and these changes are likely to place unfair burdens on our hospitals and to create barriers to access for important pharmaceutical therapies. As described in greater detail below, Premier has several concerns regarding proposals set forth by the CMS, and we recommend the following specific solutions:

(1) We strongly disagree with CMS' conclusion that prices based on the current Average Sales Price (ASP) reimbursement methodology accurately reflect hospital average acquisition costs, as required under Section 1833(t)(14)(A)(ii)(I) of the Social Security Act (SSA). As a result, the statute directs CMS to adjust one of three payment approaches listed in Section 1833(t)(14)(A)(II) to more appropriately account for hospital acquisition costs. We urge CMS to take this approach.

(2) The current ASP reimbursement methodology fails to account for the unique reimbursement issues faced by hospital outpatient departments. If CMS retains an ASP-based approach, we urge CMS to make several important refinements to the methodology. Our recommended refinements include:

- adjust the ASP methodology to more appropriately account for hospital acquisition costs by establishing a hospital "class-of-trade" ASP;
- adjust the ASP methodology by placing a limit on the percentage change that can occur for an APC for prescription drugs and biologicals from one year to another;
- adjust the ASP reimbursement level more frequently for the prescription drugs and biologicals that are paid separately under the HOPPS system; and
- adjust the reimbursement levels for prescription drugs and biologicals with the most significant inadequacies in reimbursement such as IVIG to more accurately reflect hospital acquisition costs, and support an initiative to promote channel integrity for drugs and biologicals in short supply.

(3) We support the payment and rate-setting methodologies proposed for radiopharmaceuticals, but we urge CMS to collect manufacturer sales data on these products only encompassing the hospital sector.

(4) The proposed temporary payment of 2 percent of a drug's ASP is insufficient to address costs incurred for hospital pharmacy services and medication handling in the hospital setting. We urge CMS to implement a temporary pharmacy payment of 8 percent while CMS collects more accurate cost data, and we urge CMS to accept data from the hospital community to establish a long-term solution.

Device-Related APCs

- We support the proposed changes to improve pass-through eligibility for new implantable devices. In the past, many devices were denied inappropriately because they were not inserted through a surgical incision or because CMS believed they could be placed in a previously approved, but now expired, category.

- We strongly support the use of external data to address limitations in hospital claims data and are concerned over CMS rejection of such data.

- We believe that the proposed 85 percent for hold harmless for implantable devices is inadequate considering the reductions already sustained in prior years. CMS should use external data and should increase the hold harmless to at least 95 percent.

Multi-Imaging Discount

- We recommend that CMS undertake research to determine the actual magnitude of the economies of scale and, in the interim, establish a multi-imaging discount of 25 percent rather than 50 percent.

These points are discussed in greater detail below.

I. CMS' Conclusion That ASP-Based Payment Rates Equal Hospitals' Average Acquisition Costs for Designated Drugs Is Erroneous. These Payment Rates, if Unmodified, Should Not Be Used as The Basis for HOPPS Reimbursement Rates for Prescription Drugs and Biologicals.

CMS states in the Proposed Rule that the payment rates determined under the ASP reimbursement methodology equal CMS' "best estimate of average acquisition costs for CY 2005" based on the data available to CMS through hospital claims for 2004, the hospital survey administered by the U.S. Government Accountability Office (GAO) in 2004, and the ASP payment system.[1] As a result, CMS proposes to establish the HOPPS reimbursement rates for drugs and biologicals according to the current ASP payment system.

Nonetheless, CMS' conclusion that ASP-based payment rates accurately reflect hospital acquisition costs is flawed. As a result, Section 1833(t)(14)(A)(I) of the statute specifics that CMS must not apply the ASP reimbursement methodology to the HOPPS.

Section 1833(t)(14)(A)(I), as established by the MMA, sets payment rates for 2006 for designated outpatient drugs paid under the HOPPS as equal to "the average acquisition cost for the drug for that year." The Secretary may modify these payments "by hospital group." The statute instructs the Secretary to determine each drugs' average acquisition cost, "taking into account the hospital acquisition cost survey data" gathered by the GAO as part of its study on hospital acquisition costs for prescription drugs required by the MMA.

In the event that hospital acquisition cost data are not available, Section 1833(t)(14)(A)(II) provides that payment rates shall equal "the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be." The Secretary is directed under Section 1833(t)(14)(A)(II) to adjust the average price determined

[1] 70 Fed. Reg. at 42725-6.

under these statutory payment methodologies "as necessary for purposes of this paragraph." This means that CMS may make adjustments to payment rates to more accurately reflect hospital acquisition costs.

In the Proposed Rule, CMS attempts to equate prices set under the ASP reimbursement methodology to average hospital acquisition costs so that the Agency can impose the ASP pricing system — unadjusted — on the HOPPS pursuant to Section 1833(t)(14)(A)(I). This rationale is flawed for several reasons:

- The ASP payment system was not created to determine hospital outpatient department reimbursement rates or to collect specific data on hospital acquisition costs. Without modifications, the system cannot be expected to accurately capture hospital average acquisition costs for prescription drugs as required under Section 1833(t)(14)(A)(I).

- ASP payment rates are based on weighted pharmaceutical manufacturers' average sales price to all providers. The data is neither reported by hospitals nor limited to hospital sales. The data therefore does not accurately reflect average hospital acquisition costs for prescription drugs and cannot be the basis of a payment methodology under Section 1833(t)(14)(A)(I).

- The ASP reimbursement methodology was not created with HOPPS reimbursement in mind. Congress established the payment system to set prices for Part B drugs acquired and administered by physician practices — not hospital outpatient departments. Indeed, Congress explicitly provided in the MMA that hospital outpatient departments should be reimbursed at rates equal to average hospital acquisition cost. Applying the ASP reimbursement methodology to the HOPPS without implementing modifications to account for differences among treatment settings and differences in acquisition costs likely will result in dramatic and inappropriate changes in hospitals' reimbursement rates.

- CMS' comparison of pricing data supposedly demonstrates that reimbursement rates established under the ASP payment system are comparable to the acquisition cost data reported under the hospital claims data and GAO survey. However, CMS' comparison uses ASP-based reimbursement rates that were determined with data from the fourth quarter of 2004. In other words, the data was collected before the ASP reimbursement methodology was put into place and reflects manufacturers' sales data to providers reimbursed under different payment methodologies. Prices based on this data cannot be considered to accurately reflect hospitals' average acquisition costs for 2006.

CMS' estimation that prices determined under the ASP reimbursement methodology equal hospitals' average acquisition costs also ignores the significant problems that are foreseeable as a result of the application of the ASP payment system to the HOPPS. These problems likely would not exist if the payment rates accurately reflected hospital acquisition costs.

Based on a comparison reimbursement study conducted by Premier, using the most current ASP data (3rd quarter CY 2005), we have identified a few drugs (listed below) which stand out and would be reimbursed below current acquisition cost, based on a typical patient dose, if the ASP + 6% + 2% reimbursement model is implemented in 2006.

a. IVIG 40gm dose	$422 below acquisition cost
b. Neulasta 6mg dose	$281 below acquisition cost
c. Cladarabine 3mg	$219 below acquisition cost

Hospital acquisition costs data are not available for setting reimbursement rates for prescription drugs under the HOPPS. As a result, CMS should rely on Section 1833(t)(14)(A)(II) and the payment methodologies established under 1842(o), 1847A and 1847B (modified to reflect hospital acquisition costs) for HOPPS reimbursement rates.

II. If CMS Implements the ASP Reimbursement Methodology to Set Reimbursement Rates for Designated Drugs Under the HOPPS, CMS Should Make Several Important Adjustments to Better Reflect Hospital Acquisition Costs

Section 1833(t)(14)(A)(II) enables CMS to apply the ASP reimbursement methodology established under Section 1847A, along with the payment methodologies under Sections 1842(o) and 1847B, to determine HOPPS reimbursement rates when hospital acquisition cost data is not available. Importantly, Section 1833(t)(14)(A)(II) authorizes CMS to modify payment rates established under these payment systems "as necessary" to reflect hospitals' average acquisition cost for prescription drugs. In other words, CMS is empowered to modify payment rates to reflect the full scope of hospitals' acquisition costs for prescription drugs when the ASP reimbursement methodology is implemented under Section 1833(t)(14)(A)(II).

A. CMS Should Use Its Statutory Authority to Adjust the ASP Payment Methodology to Account for Costs Specific to Hospital Outpatient Departments

In addition to the adjustments described in the prior section, CMS also should use the authority extended under Section 1833(t)(14)(A)(II) to revise the methodology used to calculate ASP payment rates for the HOPPS.

Currently, CMS calculates weighted ASP-based reimbursement rates based on manufacturers' data for sales to all providers across all classes of trade. Acquisition costs are not equal across all classes of trade. Hospitals' acquisition costs may be higher or lower than other classes of trade based on product mix, use, and volume.

Calculating ASP-based payment rates for hospitals on the basis of the prices obtained by the hospital class-of-trade would minimize these concerns. This approach also would make

ASP-based reimbursement rates under the HOPPS more reflective of hospitals' average acquisition costs.

CMS noted in the preamble to the final rule implementing the CY 2005 Physician Fee Schedule that Section 1847A "does not permit the exclusion of or differentiation by classes of trade in the calculation of the ASP payment rates" except for specific exceptions enumerated in the statute.[2] Although we disagree with this interpretation relating to the physician fee, it is quite clear that the statutory provisions governing the HOPPS invite CMS to adjust the 1847A (ASP) methodology for the hospital setting. In addition, there is nothing in the SSA prohibiting CMS from adjusting the 1847A methodology (ASP) on a class-of-trade basis for use under HOPPs.

B. CMS should adjust the ASP methodology by placing a limit on the percentage change that can occur for an APC for prescription drugs and biologicals from one year to another.

We urge CMS to implement a mechanism that protects hospitals and other providers from acquisition cost increases that exceed a designated threshold within a calendar year. Although the ASP reimbursement methodology is intended to more accurately reflect providers' drug acquisition costs compared to the Average Wholesale Price payment system.

One such solution — at least in the short-terms — is to place a percentage cap on purchase price decreases between two consecutive calendar years — would mitigate this risk. CMS could apply the **"dampening provision"** proposed in the 2003 rulemaking process to lessen the impact of dramatic reductions in payment rates for these drugs and biologics. CMS stated that the dampening option "mitigates the potential for underpayment" in cases where "costs show significant fluctuations.

C. CMS should update the ASP more frequently for some or all of the prescription drugs that are paid separately under the HOPPS system.

Premier also recommends that CMS modify the ASP reimbursement methodology so that reimbursement rates are updated more frequently for the hospital outpatient department setting. In practice, updates to the ASP-based payment rates are made two quarters after the data is collected, such that first quarter 2006 payment rates will be based on data from the third quarter of 2005.

Using its authority to adjust the frequency with which ASP-based reimbursement rates under calculated under the HOPPS, CMS should reduce the lag between sales data collection.

D. CMS Should Use Its Statutory Authority to Adjust the Reimbursement Rates for Specific Drugs and Biologicals

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[2] Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Final Rule, 69 Fed. Reg. 66235, 66301 (Nov. 15, 2004).

This statutory authority enables CMS to adjust payment rates for individual drugs significantly affected by the ASP payment system and to prevent the development of access issues for beneficiaries who require prescription drugs adversely affected by the ASP reimbursement methodology. For example hospitals' acquisition costs for Intravenous Immune Globumin (IVIG) are climbing faster than reimbursement rates are adjusted under the ASP pricing system.

Implementing the ASP payment system under Section 1833(t)(14)(A)(II) would enable CMS to modify the payment rate for IVIG and other similarly-situated drugs so that hospitals are adequately reimbursed for the administration of these drugs.

In addition, for products that are in short supply, such as IVIG, Premier urges CMS to engage FDA and other interested parties to develop better policies and regulations to promote and improve channel integrity for pharmaceuticals and devices.

III. Radiopharmaceuticals

We support the payment and rate-setting methodologies proposed for radiopharmaceuticals. In 2006, these products would be paid based on a hospital's charges reduced to costs and ASP reporting would be initiated. Although we agree with this policy, we urge CMS to collect manufacturer sales data on radiopharmaceuticals only pertaining to the hospital sector.

- Premier also recommends that CMS consider applying the same payment methodology proposed for radiopharmaceuticals to IVIG as an alternate option to address the inadequate payments for certain drugs and biologicals, such as IVIG.

IV. CMS' Proposed Pharmacy Overhead Fee Is Inadequate to Cover Hospital Outpatient Departments' Pharmacy Overhead and Handling Costs, and CMS Should Implement an Overhead Fee Equal to 8 Percent

Premier supports CMS' efforts to establish a payment rate that serves as a proxy payment for pharmacy overhead costs during the two years that CMS collects data on hospital pharmacy costs associated with overhead, handling costs and drug preparation, delivery and administration. However, this proxy payment is insufficient to cover all of the intended costs, and we recommend that CMS implement a proxy payment rate of 8 percent instead.

Premier is extremely concerned that the proposed 2 percent add-on for non-drug pharmacy costs does not adequately recognize the cost that hospital pharmacies incur in making drugs available to hospital outpatients. We believe that prior studies, the recent MedPAC report and other concurrent studies all show the add-on percentage should be substantially higher. MedPAC, for example, found that wage and salary costs, fringe benefits, and pharmacy supplies – in other words, direct costs – comprise approximately 25 percent of pharmacies' total costs. Thus, an add-on to the drug portion, which is about 75 percent of total costs, would need to be 33 percent to reimburse 100 percent of costs.

Therefore, Premier strongly recommends that CMS increase the proposed 2 percent add-on substantially. Premier agrees with the results of the recent ACCC study which recommends an add-on of 8 percent. The 8% add-on payment would add $90 million to spending before budget neutrality. The required budget neutrality adjustment would be a reduction of less than 0.4 percent. In contrast the budget neutrality adjustment in the proposed rule would be an increase of 0.38 percent. The budget neutrality adjustment required represents a figure that is well below the budget neutrality adjustments applied to the OPPS rates in 2003, 2004 and 2005. For comparisons the budget neutrality adjustments in prior years were 1.53 percent in 2005, 1.84 percent in 2004, and 3.1 percent in 2003.

* * * *

New Implantable Devices Are Denied Pass-Through Eligibility

We support the proposed changes to improve pass-through eligibility for new implantable devices. In the past, many devices were denied inappropriately because they were not inserted through a surgical incision or because CMS believed they could be placed in a previously approved, but now expired, category. Premier supports CMS' proposal to modify its interpretation of the criteria used to consider a new device category when the item is not surgically inserted or implanted but is inserted through a natural body orifice. Asserting that devices which are inserted through a natural orifice offer important benefits to Medicare beneficiaries, such as avoidance of more costly and more invasive surgery, CMS proposes to include devices that are inserted or implanted through a natural orifice or a surgically created orifice (such as through an ostomy) within the scope of surgically implanted devices, as well as those that are inserted or implanted through a surgically created incision.

Premier also supports CMS' proposal to address concerns that several of the existing and previously existing device category descriptors are overly broad and may preclude some new technologies from qualifying for establishment of a new device category for pass-through payment. In the proposed rule, CMS recommends creating an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment. The new category would be used in instances where CMS believes that an existing or previously existing category descriptor does not appropriately describe the new type of device. Premier was one of the commenters who had presented this problem to CMS in the past and we support the proposed change.

Use Of External Data To Address Limitations In Hospital Claims Data

Premier continues to strongly support the use of external sources of data to supplement hospital claims data. We note that the APC Advisory Panel continues to recommend that CMS address the problem of missing and erroneous device data by incorporating external data into median cost calculations. We strongly urge CMS to return to the policies it employed in 2003 and 2004, but rejected in 2005. OPPS claims data used to set payment rates continue to be inadequate and lead to unrealistically and unacceptably low payment rates. OPPS data have not improved significantly since the years in which external data were used. Thus, we strongly urge CMS to continue to use external data both for previously-adjusted APCs, as

well as for those APCs that have been reduced in the NPRM and/or have been underpaid since the start of OPPS. In many cases, these data are vastly superior to the cost estimates CMS derives from billed charges.

Implantable Devices and the Proposed 85 Percent Hold Harmless

We believe that the proposed 85 percent for hold harmless for implantable is inadequate considering the reductions already sustained in prior years. CMS should use external data and should increase the hold harmless to at least 95 percent. Without a change in these policies, patients could experience diminished access to these services, or the services could move to the inpatient setting with increased cost to the Medicare program.

Multi-Imaging Discount

Although Premier agrees that there likely are economies of scale in performing certain multi-imaging procedures, we believe that the 50 percent reduction proposed in the NPRM is arbitrary and lacks empirical justification. The justification for the 50 percent reduction appears to be based on a loose analogy with the practice expense portion of the physician fee schedule. Premier does not believe that constitutes an acceptable basis for cutting hospital payments by 50 percent. We are very concerned that overly large and unjustified reductions could hinder patient access to necessary imaging. We recommend that CMS undertake empirical research to determine the actual magnitude of the economies of scale when multiple imaging procedures are performed in a hospital. In the interim, CMS could establish a multi-imaging discount of 25 percent rather than 50 percent as proposed. Finally, Premier urges CMS to work with hospitals and physician specialties to refine the families of procedures that define which procedures are subject to the discount.

Thank you again for the opportunity to comment on the proposed rule on Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. If we can be of further assistance or if you would like to discuss our comments further, please do not hesitate to contact me at (202) 879-8003 or Margaret_reagan@premierinc.com.

Sincerely,

Margaret R. Reagan
Corporate Vice President
Premier, Inc.

[1] 68 Fed. Reg. 4798, 48003 (Aug. 12, 2003).

[2] 70 Fed. Reg. at 42725-6.
[3] Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Final Rule, 69 Fed. Reg. 66235, 66301 (Nov. 15, 2004).

208-D

On behalf of 10 Constituents

JERRY LEWIS
41st DISTRICT, CALIFORNIA

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(WITHIN CALIFORNIA)
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Congress of the United States
House of Representatives
Washington, DC 20515-0541

July 1, 2005

PBT Hunter
NTAPC Ahmed
APC 6w Buzy

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 314G
Washington, D.C. 20201

Dear Dr. McClellan:

I am writing to express my support for CMS continuing the current payment rates for the delivery of proton beam therapy. Any decrease in reimbursement would negatively impact Loma Linda University Medical Center (LLUMC), located in my Congressional district. LLUMC is the leading clinical and research center for the emerging development of proton centers in the country and currently provides proton therapy for over 140 patients per day.

It is important to maintain the current reimbursement for intermediate and complex proton therapies in the New Technology APC 1510 at the rate of $850. Proton therapy meets the criteria for a New Technology because it is relatively new service – only currently offered by three facilities. Also, proton therapy is not adequately represented in the claims data used to set the proposed and final payment rates for 2006.

Proton beam therapy, and its emerging technologies, is critical to providing successful cancer treatment without adverse side effects and with comparable cure rates to the "Gold Standard." Proton therapy already provides many clinical benefits over conventional radiation and surgery, and the new dose modulation therapy will expand the reach of treatment to patients with cancers that are more advanced as well as breast and lung cancers.

Proton therapy is responsible for improving the quality of life for thousands of cancer patients and raising the standard of treatment. Appropriate payment rates will ensure that this leading-edge cancer therapy will be available to those in need.

Thank you for your consideration of this vital matter.

Sincerely,

Jerry Lewis

Jerry Lewis
Member of Congress

UNIVERSITY OF CALIFORNIA

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Impact
Outlier
APC Weights
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Kane
Sanaco
Hart
Bazell
Ritter
Heygster
Ahmed

September 14, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Ave, SW
Washington, DC 20201

SUBJECT: **CMS-1501-P** – Proposed Medicare Hospital Outpatient Prospective Payment System Rates for Calendar Year 2006

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Medicare Outpatient Prospective Payment System (OPPS) proposed rule for Calendar Year (CY) 2006 issued by the Centers for Medicare & Medicaid Services (CMS) in July 2005. These comments are provided on behalf of the University of California (UC), Office of the President, Clinical Services Development Division, and UC's five academic medical centers (AMCs) located in Davis, Los Angeles, Irvine, San Diego, and San Francisco.

Together, the UC AMCs are the fifth largest healthcare delivery system in California, the leading provider of certain specialty services and medical procedures, and one of the state's largest providers of care to Medicare patients. Annually, the AMCs provide patient care services valued at over $3.3 billion. In alignment with its patient care work, the AMCs also play a critical role in a number of broad public-policy goals, including the education of health professionals and the advancement of medical science through cutting-edge research. Specifically, UC medical centers offer services that are essential to the health and well being of Medicare beneficiaries including a broad-array of highly specialized services, such as cancer centers, geriatric and orthopedic centers of excellence, organ transplant programs, and world class primary and preventive care.

The University is extremely concerned with the decline of its Medicare payments given our role in providing medical education and in serving extremely high-cost Medicare beneficiaries. In fiscal year 2004, the UC Medical Centers incurred aggregate Medicare OPPS losses in excess of $40 million. These losses threaten the viability of our clinical enterprise and our role as teaching hospitals. UC continues to urge Congress to provide adequate Medicare payments to its hospitals and urges CMS to ensure the Congressional intent of hospital payment updates is fully implemented on a programmatic level. Further, while UC's comments address the most significant areas of concern for its AMCs, it urges CMS to make changes to the proposed rule that would prevent further decline in Medicare payments to its medical centers.

- OPPS Payment Updates

The proposed rule follows the current law requirement that the base payment rate be increased to reflect the full hospital inpatient market basket of 3.7 percent for FY 2006. However, the CMS data indicates that the actual average outpatient payments will increase only by an estimated 1.9 percent because of the expiration of several Medicare Modernization Act (MMA) provisions. This reduction will be exacerbated for teaching hospitals by the changes to the wage index calculation. **The UC respectfully requests that CMS provide detailed information on how it derived its impact estimates.**

- Outlier Payments

Outlier payments are a critical component of the PPS. For the UC hospitals, the outliers help mitigate the financial losses of high-cost cases. For 2006, CMS proposes to set the target for aggregate outlier payments at 1.0 percent of aggregate total payments under OPPS. Further, to ensure that estimated 2006 outlier payments would equal one percent of total outpatient PPS payments, CMS proposes to increase the fixed-dollar threshold to $1,575, while maintaining the multiplier threshold at 1.75. UC is concerned that the threshold may be too high and may result in aggregate outlier payment amounts that are less than the budget neutrality target. Further, the proposed rule contains no analysis on the redistributive impact of these proposed changes. **The UC respectfully requests that CMS publish data to evaluate the proposed rule before any changes are implemented.**

- Adjustments for Certain Hospital Categories

Under current law CMS is allowed to adjust the payment system in a budget neutral manner if it determines such adjustments are necessary to ensure equitable payment distribution. Unfortunately, the proposed rule includes no discussion of the special role and costs related to medical education. **The UC respectfully requests that CMS conduct an analysis to determine the appropriateness of including a teaching adjustment.**

- APC Relative Weights, Grouping, and Payment Rates

Current law requires the review and revision of the relative payment weights for Ambulatory Payment Classifications (APC) at least annually. The proposed rule includes a number of coding, APC assignment, and "pseudo single claim" changes. The UC is concerned that these changes may adversely impact payments for high volume and costly outpatient services.

The UC AMCs have worked aggressively to ensure patients are placed in the most appropriate clinical setting and adopted new costly technologies designed to improve patient care. Many of these efforts emphasize outpatient services to Medicare beneficiaries, help improve access, and address capacity issues. It is critically important that the OPPS not penalize hospitals, such as the UC, for efficient treatment and for ensuring that patients receive the right care at the right time in the right place.

The UC respectfully requests that CMS provide additional information on the impact of each of the proposed policy change and information on the combined impact of all changes. We also request that CMS provide a public use file that demonstrates the impact of each proposed change to enable providers to review these impacts, assess the impact on their operations, and provide a basis for providing thoughtful comments to CMS.

- Payments for Drugs and Biologicals

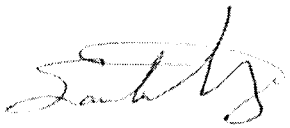
The proposed rule would continue to pay hospitals separately for drugs and biologicals whose per day costs exceed $50 or bundling the payment with the appropriate procedure code when the drugs cost less than $50. The MMA provided that for CY 2006, payment payable for drugs and biologicals be equal to the average acquisition costs adjusted for overhead costs. Conversely, the current payment method is based on average wholesale price. CMS has determined that the average acquisition costs for drugs and biologicals is equivalent to the average sales price (ASP).

The payment under the proposed rule would be ASP plus 6 percent for acquisition costs and 2 percent to cover hospital handling costs. This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP plus 8 percent, which is a rate that CMS indicates is equivalent, on average, to the mean cost for drugs derived from hospitals claims data. The UC agrees that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare.

We recommend that the 2 percent adjustment for drug handling be treated as a temporary measure until CMS develops an approach to establish differential add-on payments for drug handling costs to account for a wide variety of drug handling categories.

Thank you for the opportunity to comment on the Medicare Outpatient PPS proposed rule for CY 2006. If there are questions or if I can provide any additional information or input, please contact me at 510-987-9062 or santiago.munoz@ucop.edu.

Sincerely,



Santiago Muñoz, Executive Director
Clinical Services Development

Barco, Evell J. (CMS/OSORA)

From: Sanow, Joan H. (CMS/CMM)
Sent: Saturday, September 17, 2005 9:37 PM
To: KANE, REBECCA (CMS/CMM); Hart, James L. (CMS/CMM); Barco, Evell J. (CMS/OSORA)
Subject: FW: Comments on CMS-1501-P
Attachments: Medicare OPPS 2006 Comments.pdf

From: Cindy Williams [mailto:cindy.williams@ucop.edu]
Sent: Friday, September 16, 2005 5:44 PM
To: Sanow, Joan H. (CMS/CMM)
Subject: Comments on CMS-1501-P

Dear Ms. Sanow,
Frank Camozzi in your SF office suggested I send you a copy of our comments on "CMS-1501-P, Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates." I called the SF office because I submitted our comments this afternoon and have not received the automatic reply confirming they were received. I do have a copy of a "Docket Management Comment Form," that was generated and assigned a temporary comment number, and I hope that sending you this copy, also, will assure that our comments get in.
Thanks,
Cindy Williams

Cindy Williams
Clinical Services Development
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Oakland, CA 94607-5200
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Fax: (510) 763-4253
cindy.williams@ucop.edu

Joan forwarded this comment to us.

HUMILITY OF MARY
Health Partners

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Imaging

Kaine
Sarau
Hart
Bazell
Hunter

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

I am writing on behalf of St. Elizabeth Health Center in Youngstown, Ohio on an issue of great importance to Medicare beneficiaries with cancer. St. Elizabeth Health Center is one of the leading institutions and research centers for cancer care. Positron emission tomography (PET) technology scans are an integral part of the St. Elizabeth program to diagnose and manage patients with cancer. We are pleased that the Centers for Medicare and Medicaid Services (CMS) have recently proposed to expand cancer coverage for PET scans. We are concerned, however, that the proposed hospital outpatient payment rate for PET/CT scans is inadequate to cover hospital costs for this new technology.

The PET/CT scanner is the latest advance in oncology imaging which combines two state-of-the-art imaging modalities. PET is a highly sensitive technique that detects the metabolic signal from actively growing cancer cells in the body. The key to PET's effectiveness is that it provides physicians with information about the body's chemistry, cell function, and metabolism that anatomic imaging modalities such as CT and MRI are unable to provide. The PET scan does not provide the exact anatomic location of the signal in the body. CT provides high resolution anatomic information regarding the location, size, and shape of various lesions, however it cannot differentiate cancerous lesions from normal structures with the same accuracy as PET. The combined PET/CT scanner merges PET and CT images together, thereby more accurately identifying and localizing tumors in the body.

Last year, CMS in the Hospital Outpatient Rule decreased payment rates for PET scans from $1375 to $1150. This decreased rate has challenged our ability to provide PET scans to medical beneficiaries. We applaud the CMS decision in the proposed rule to keep stable the payment rate for PET scans, thereby avoiding further constraints on providers' ability to offer this service.

St. Elizabeth Health Center
1044 Belmont Avenue / Youngstown, Ohio 44501 / (330)746-7211

MEMBER OF CATHOLIC HEALTHCARE PARTNERS
Teaching hospital affiliate of Northeastern Ohio Universities College of Medicine

We are concerned, however, about the proposed payment rate for PET/CT. The PET/CT scan is the leading diagnostic imaging tool for managing patients with cancer. The proposed payment rate of $1250 is well below our cost for these scans. Without adequate reimbursement, beneficiary access to PET/CT will be limited.

I urge you to keep the hospital outpatient payment rates for PET scans stable and to increase the payment rate for PET/CT to represent true costs for hospitals.

Thank you very much for your attention. Please feel free to contact me with more information at 330-480-2220.

Very truly yours,

Albert J. Cook, II, M.D., Chairman
Department of Radiology
St. Elizabeth Health Center

Rec'd 9/15/05 J.N.W.

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September 15, 2005

IHA

Dr. Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.,
Washington, D.C. 20201

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ATTN.: CMS-1501-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, Federal Register, Volume 70, No. 141, Monday, July 25th, 2005

Dear Dr. McClellan:

On behalf of our approximately 190 member hospitals or health care systems, the Illinois Hospital Association (IHA) is taking this opportunity to formally comment on the proposed rule establishing new policies and payment rates for hospital outpatient services for calendar year 2006. The outpatient prospective payment system implemented in August 2000 continues to present a significant challenge to hospitals; thus, IHA applauds CMS for its conscientious efforts to improve the system. The Association presents the following comments for your consideration:

PAYMENT PROVISIONS:

- CMS indicates that it will use the final hospital-specific wage indices as determined from the inpatient acute prospective payment system final rule. For FY 2006, this index will be based on Core-Based Statistical Areas (CBSA) data exclusively. The Illinois Hospital Association supports the consistent usage of wage index data among the various prospective payment systems.

- CMS has proposed an increase in the payment rates by 3.2%, the full market basket increase as required by current law. However, the final rule for inpatient acute services increased the estimate of the full market basket percentage to 3.7% in accordance with more current cost data. IHA expects that this same adjustment to the market basket forecast will be applied to the OPPS when the final rule is published.

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- CMS is proposing to reduce the payment for partial hospitalization (PHP) by 15% to account for pricing differences the agency believes are present in PHP programs operated by community mental health centers (CMHC), as well as substantial differences in costs between hospital-based and free-standing programs. Consequently, the proposed per diem rate for PHP services in FY 2006 is $240.51, a significant reduction from the FY 2005 amount of over $280. IHA strongly objects to such a drastic payment reduction in one year. Several hospitals in Illinois have discontinued their partial hospitalization programs within the past several years, primarily for financial reasons. A further payment reduction could only serve as an impetus for other facilities to scale back, if not completely close down their programs. Access to this much needed service on the part of Medicare beneficiaries is already strained. Therefore, the Illinois Hospital Association recommends that CMS re-visit its pricing and costing data and, if a reduction is necessary, implement a percentage reduction that is no more than 5% in any one year.

- CMS has proposed reducing the total outlier pool in FY 2006 to 1% of total outpatient payments from 2% in FY 2005. In order to achieve the 1% spending target, CMS has proposed increasing the fixed dollar threshold to $1,575, $400 higher than the threshold applied in FY 2005. Therefore, to be eligible for an outlier payment in 2006, the cost of the service must exceed 1.75 times the Ambulatory Payment Classification (APC) payment rate and it must also be at least $1,575 more than that APC amount. The outlier payment amount would equal 50% of the difference between the computed service cost and 1.75 times the APC payment amount. The Illinois Hospital Association suggests that CMS verify that its data, in particular its charge data, are as current and accurate as possible. Hospitals' pricing policies have changed since 2003 as a result of revisions to the Medicare inpatient outlier payment calculation which CMS implemented. Comparatively lower percentage increases are being instituted and some hospitals have even reduced their prices. So unless CMS uses an accurate hospital price database, the agency could inadvertently be setting its fixed threshold amount ($1,575) artificially high.

- In accordance with the MMA, CMS is proposing to sunset transitional corridor payments for rural and sole community hospitals through December 31st, 2005. These payments are meant to provide financial relief to those rural hospitals that are receiving less under OPPS than they were under previous reimbursement methodologies. The proposed rule discusses a cost study performed by CMS during 2004-05; the results of that study have been incorporated into the FY 2006 payment rule. While CMS has proposed some financial relief to rural sole community hospitals by increasing their OPPS payments by 6.6% (except for drugs and biologicals), it further states that there were no significant cost differences between other rural hospitals and urban hospitals that would necessitate

a payment adjustment for rural hospitals other than sole community hospitals. While the Illinois Hospital Association supports the payment add-on for sole community hospitals, it encourages CMS to continue to study cost differences among hospitals, most notably, other rural hospitals, and to implement payment relief for those other rural hospitals as warranted.

Dr. McClellan, thank you again for the opportunity to comment. The Illinois Hospital Association welcomes the opportunity to work with your agency in the continued development, refinement and reform of the Medicare payment system.

Sincerely,

Thomas A. Jendro
Senior Director-Finance
Illinois Hospital Association
(630) 276-5516
tjendro@ihastaff.org

UPMC | University of Pittsburgh Medical Center

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September 15, 2005

PHP
Imaging
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APC Weights
Outlier

Kane
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Ahmed
Heygster
Riffer

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Pittsburgh, PA 15213-2582

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Mail Stop: C4-26-05
Baltimore, MD 21244-1850

ATTENTION: CMS-1501-P

RE: CMS-1501-P
Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Rates; Proposed Rule

Dear Sir or Madam:

On behalf of the University of Pittsburgh Medical Center (UPMC) we are submitting one original and two copies of our comments regarding the Center for Medicare and Medicaid Services (CMS) proposed rule (70 FR 42673-43011, 7/25/2005) "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Rates."

The following is a summary of UPMC concerns and issues with the FY2006 proposed rules.

1. **Partial Hospitalization** (Page 42692)

Proposed CY 2006 Rule: In this year's proposed rule CMS indicated that as a result of the volatile cost data for CMHC's partial hospital program (PHP) services (fluctuating from a high of $1,037 to a low of $143) CMS has proposed to apply a 15% reduction to the combined hospital-based and CMHC median per diem CY 2005 PHP rate, for CY 2006. This would amount to an approximate partial hospital program (PHP) service rate for CY 2006 of $240.51. (I.e. CY 2005 rate $289 * 85% = $245.65, $240.51 after scaling but before wage index adjustments.)

Response: We do not support the 15% payment rate reduction for CY 2006 partial hospital program (PHP) services. Instead we urge CMS to take last years approved rate of $289 and inflate it by the overall net market basket increase of 4.15%, for a PHP rate of $300.90. We do not believe that the alternative approach suggested by CMS of basing the payment on solely the hospital-based cost data is a viable option either, since the

CMHC service costs have almost always exceeded the Hospital-based costs. This would clearly result in an underpayment to the CMHC providers.

2. **Outlier Payments** (pages 42701 – 42702)

Proposed Rule: CMS proposed to reduce the projected outpatient outlier payment target pool from a CY 2005 level of 2% to 1% for CY 2006. In addition CMS has proposed increasing the fixed dollar threshold from $1,175 to $1,575. CMS indicated that they would ultimately like to eliminate all outpatient outliers as recommended by the Medicare Payment Advisory Committee (MEDPAC).

Response: We urge CMS to reverse both of these proposed outlier changes, and restore the outlier payment levels to a target level of 3.0 percent as established under the Balanced Budget Refinement Act of 1999. Conceptually, outlier payments serve as insurance in protecting hospitals against unexpected, large losses at the service level since the APC payment is based on average costs. We believe that this payment protection is still necessary and should not be eliminated.

3. **Multiple Diagnostic Imaging Procedures (page 42748)**

Proposed Rule: CMS proposed to make a 50-percent reduction in the OPPS payments for some second and subsequent imaging procedures performed in the same session, within each "family" of imaging procedures by imaging modality. CMS contends that these secondary imaging procedures should cost less than the first image taken, since efficiencies are gained when performing multiple family imaging. (11 families identified - Ultrasound, computerized tomography (CT) and computerized tomography angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) and various contiguous body areas as indicated on table 32, page 42749.)

Response: We believe this proposed payment policy change for multiple imaging services incorrectly penalizes hospitals with reduced imaging payments on select services, and should not be adopted by CMS. CMS contends that the secondary imaging procedure should cost less than the first image taken, since efficiencies are gained when performing multiple family imaging. While this may be true, the carve out of only select services with potential lower than average costs ignores the fundamental principal of "average costing" and the application of the overall departmental "cost-to-charge ratio" (CCR). Medicare determines each ambulatory payment classification (APC) weight based on the median cost of service in each APC, as determined by applying each facilities average departmental CCR to each departments procedure charge. Since each departmental RCC was determined by taking "all allowable department costs" divided by departmental charges, any subsequent payment reduction from this average cost ratio will consequently create an understatement of costs for the more intense department services which were also costed with this same average RCC. As such, the carve out of select multiple services for reduced payments (as CMS proposed above) would create payment shortfalls for other more intense services which would have been understated by the application of the average costing methodology which occurs when applying the average

CCR's. For this reason we contend that CMS should not adopt this proposed rule, as a one-sided intensity review unfairly penalizes providers.

4. **Lack of Teaching Adjustment in the Outpatient Perspective Payment System** (not in rule)

Proposed Rule: None.

Response: We would urge CMS to consider incorporating an IME teaching adjustment into the OPPS since it is the only major Medicare payment system that does not include a teaching adjustment.

5. **"Non-Pass-Throughs" - Proposed Coding Changes for Drug Handling Costs (pages 42728 – 42731)**

Proposed Rule: CMS is proposing to change the CY 2006 OPPS payments for separately payable drugs, biologicals, and radiopharmaceuticals from its current average wholesale price (AWP) to the average sales price (ASP) plus 6 percent. (This is the price paid in physicians office settings.) In addition CMS is proposing to pay an additional 2 percent for overhead and handling costs. This proposal also establishes 3 new C-codes for drug handling categories to identify the administrative costs for the drugs and biologicals.

Response: We do not support the establishment of these new C-codes to track the administrative handling costs for drugs and biological, at this time, and urge CMS to work with the Association of American Medical Colleges (AAMC) to look into other method to gather this data. Our coding department has expressed concern that the proposal as outlined is to complex and cumbersome for our current billing system and prefer a simpler approach. In addition the current proposal to pay an additional 2-percent for drug handling costs appears to be inadequate to cover the overhead and handling costs of drugs and biologicals. We believe more study is necessary and do not support this proposal at this time.

Conclusion

We appreciate the opportunity to submit this comment on your proposed changes on the Hospital Outpatient Prospective Payment System for fiscal year 2006 and hope that is considered before any final rules are published.

If you have any questions regarding our comments please telephone me at (412) 647-8695.

Sincerely,

Paul Stimmel

Paul Stimmel
Senior Analyst, Special Projects Department

Cc: T. Nigra
E. Karlovich

FLORIDA HOSPITAL ASSOCIATION
An Association of Hospitals & Health Systems

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September 15, 2005

Observation
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APC weights

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Kane
Sanow
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Hostetler
Hunter
Ahmed
Burley

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1501-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: [CMS-1501-P] Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (70 *Federal Register* 42673), July 25, 2005

Dear Dr. McClellan:

The Florida Hospital Association, on behalf of its member hospitals and health systems, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' proposed Medicare outpatient prospective payment system (OPPS) rule for calendar year 2006, as published in the *Federal Register* dated July 25, 2005. Since its implementation, the outpatient prospective payment system has presented significant implementation challenges to hospitals, to CMS, and to the intermediaries. We have been faced with repeated clarification and revision of policy, a trend that would continue under the proposed rule for 2006.

In addition to the lack of a payment system that is consistent from year to year and devoid of significant changes, there are several areas of concern with the provisions included in the proposed rule for calendar year 2006. These include observation services, hospital coding for evaluation and management services, payment for outliers, payment for pharmacy overhead and drug handling costs, and reduced payment for multiple imaging procedures. These concerns and comments are detailed below –

Observation Services

CMS established separate payment for observation services under the OPPS for three medical conditions: chest pain, congestive heart failure, and asthma. For calendar year 2006, CMS proposes to shift the determination of whether or not observation services are separately payable from the hospital billing department to the claims logic contained in the Outpatient Code Editor (OCE). While we support the concept of allowing the OCE logic to determine whether services are separately payable, we question the need for a specific HCPCS code for "direct admission of patient for hospital observation care." The determination of an admission to observation through the emergency department rather than a direct admission could be made based on the presence or absence of specific revenue codes on the outpatient claim, such as 45X to indicate emergency department or 516 for urgent care center.

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Hospital Coding for Evaluation and Management Services
The FHA encourages CMS to move ahead in issuing a proposed national, uniform evaluation and management (E&M) coding system for hospitals. It will take providers a minimum of 6 months after release of a final rule on E&M facility coding to train their staff and modify internal systems before we could move to a standard. The longer the delay in publishing even a proposed rule, however, the more concerned we are with HIPAA compliance.

While CMS can say that the coding structure that is currently in place – every hospital developing its own definition for established CPT codes – has been approved by CMS, it has not been approved by the myriad of other payers that hospitals also bill. These payers are billed with the same CPT codes – with the hospital-defined matrix for placing a patient in a particular level – and this is in violation of HIPAA transaction and code set regulations that indicate use of a particular code set pertains to both the code and its definition as published by the maintainer (the AMA in the case of CPT codes). To instruct and to continue to allow hospitals to "make up their own" definition for these established CPT codes is not HIPAA-compliant. In addition, using these codes with their hospital-devised definitions for claims submission to other payers is not appropriate under the HIPAA standards.

Payment for Outliers
The proposed rule would decrease the act aside for outlier payments from 2 to 1 percent and increase the dollar threshold for receiving outlier payments to $1, 575. We are concerned that the proposed threshold is too high and request that CMS share the details of how the threshold was established.

Pharmacy Overhead and Drug Handling Payment Adjustments
The proposal to pay hospitals for the costs associated with pharmacy overhead and drug handling/preparation costs follows an earlier recommendation from the Medicare Payment Advisory Commission (MedPAC). While we support the concept to pay hospitals for these costs, we have serious concerns with the proposed charging system to identify handling and overhead separate from the drug charge. The vast majority of payers do not accept the C-codes and, therefore, the proposed separation of charges would be in conflict with the existing Medicare requirements to maintain "like charges for like services" when we would have to bill a drug rate inclusive of handling costs to most payers and to remove this handling charge and bill it separately to Medicare.

Reduced Payment for Multiple Imaging Procedures
CMS proposes to reduce the payment when multiple imaging services are provided as part of the same encounter, with full payment for the highest paid imaging service and a 50 percent reduction in the payment for additional procedures in the same family of procedures. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents an appropriate measure of multiple procedures efficiencies. The discount level was determined by using the Medicare physician fee schedule practice expense data rather than hospital service cost data. The existing APC weights were established by using hospital costs for individual services –

costs that would already reflect the efficiencies gained when multiple procedures are performed during a single encounter within the hospital setting.

Proposed Changes to Packaged Services

While CMS has addressed some packaged services and identified instances in which they will be eligible for separate payment, we would urge inclusion of 75893, Venous sampling by catheter, and 36500, Insertion of catheter, vein, in the list of codes that, although usually packaged, would be separately payable when there are no other separately payable services on the claim. It is our understanding that many times these are the only procedures that the patient is having. The supervision and interpretation (S&I) code 75893 includes any related venograms that are done at the same time as the venous sampling, so you would not use the separate venogram codes with these procedures. As the program currently exists, unless you use the venogram code in addition to the venous sampling code, there is not a payable procedure, and, in reading the CPT description, inclusion of both codes should produce a "component of" edit. We would request that CMS look at these additional codes for packaged services and consider establishing a separate payment for them when there are no other separately payable services on the claim.

Again, the Florida Hospital Association appreciates the opportunity to provide these comments on the proposed rule for outpatient prospective payments for calendar year 2006. If there are any questions on these comments, please do not hesitate to contact me at (407) 841-6230.

Sincerely,

Kathy Reep

Kathy Reep
Vice President/Financial Services

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PHP

Baker Community Mental Health Center

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Baker, LA. 70704-0668 Baker, LA. 70714
PHONE: 225-771-1510 FAX: 225-771-1520

"Help when it's needed most"

Kane
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September 14, 2005

RE: Comment to CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates – Proposed Rule

To Whom It May Concern:

Our agency, Baker Community Mental Health Center, is a freestanding community mental health center in Baker, Louisiana. We serve approximately 25-30 patients on a daily basis. We employ approximately 20 employees and contract workers in our community. We provide intensive psychiatric programs that are much needed by the patients in our community.

For instance: 1). We treated a 63 year old, black male, for major depression with psychotic features who was referred by his PCP and family for increasing inability to sleep at night and paranoia in spite of medication. He was taught relaxation techniques, stress management and was able to improve his coping skills as well. 2). We treated a 38 year old, white female, for Schizo-affective disorder, bi-polar type who was referred by her PCP and nursing home staff. She had a long history of mental illness, inappropriate behavior and depression symptoms. In the past, this patient required hospitalization when she started decompensating. This time, she was admitted to PHP, medication was adjusted, and she participated in group therapy. After several weeks in the program, she became stable and behaved appropriately. Inpatient treatment was prevented. 3). Treated a 67 year old, black female, for major depression with psychotic features having difficulty dealing with the death of her 2 sons. She had poorly controlled diabetes due to inability to keep up with her diet due to depressive state. Once started on medication, she became involved with group therapy and started showing much improvement until her third son was murdered. She became very depressed to the point of requiring inpatient treatment. The patient continued with the PHP and on a daily basis with support of staff and peers she was able to improve to the point that inpatient treatment was not necessary.

We are requesting the proposed 15% cut for our program be stopped. The current payment rate is not sufficient to cover the costs needed for our intensive programs. Our costs are higher than hospitals who share and spread their costs to other departments. Our patient acuity level is also more intense than the hospital patients receiving one or two therapy sessions.

This service is especially needed for our rural communities who are not serviced by hospital programs. Additionally, our state does not offer this program as a Medicaid service.

MAYO FOUNDATION

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September 15, 2005

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Baltimore, Maryland 21244-1850

We appreciate the opportunity to comment on the Proposed Rule of July 25, 2005 regarding changes to the Hospital Outpatient Prospective Payment System utilizing ambulatory payment classifications (APCs). The following comments are offered for your consideration:

Multiple Diagnostic Imaging Procedures

CMS states that under APC payment methodology, Medicare payment rates are based on the premise that each service is being performed independently and that rates do not account for efficiencies that may be gained when multiple studies using the same imaging modality are performed in the same session. Those efficiencies are especially likely when contiguous body areas are the focus of the imaging, because the patient and the equipment have already been prepared "potentially" yielding resources savings in areas such as clerical time, technical preparation and supplies.

We respectfully disagree with CMS assertion that the APC payment rates do not reflect the efficiencies that may occur when multiple studies are performed in the same session. When CMS recalibrates the APC payment, each hospital's claim has its charges reduced to costs based on the specific cost-to-charge ratio. The costs in this ratio already reflect the efficiencies achieved during multiple imaging sessions. Since the reduced costs are in the cost-to-charge ratio and the median costs are reflected in the APC relative value, there is no need to further reduce an APC payment based on multiple procedures occurring in the same session. To do so would further reduce payment for costs that have already been reduced. If the relative value of the APC was determined through a mechanism that did not already account for the reduced level of costs, then, there may be a rationale to provide a reduced level of payment for a second procedure.

CMS states they do not believe these same inputs are needed to perform multiple procedures on the same day. CMS is proposing a 50 percent reduction in the technical payment for these services although CMS presents no hard data that would support a 50 percent reduction for radiology other than that there is some duplication of effort and "potential" savings. Prior to implementing such a drastic reduction in payment for these services, we recommend that CMS conduct a valid study to measure the timesavings and practice expense reduction involved in performing multiple procedures within each of these families. We see no solid justification for a 50 percent reduction in reimbursement. Instead, CMS is basing this decision on recommendations from MedPAC. MedPAC states that there are savings in clerical time,

preparation and supplies when patients have multiple studies of the same modality performed on contiguous body parts. MedPAC goes on to state that since CMS has a policy of reducing payment for multiple surgical procedures, they should have this same policy for radiology imaging services. To compare radiology imaging services to surgical services is not a reasonable comparison. The savings on multiple surgical services can be tied directly to the timesaving related to the surgical opening and closing of the patient. To what extent this is true for the radiology services listed is unknown.

We would argue that the work effort involved for the technologist does not change significantly when doing multiple areas. For example if a CT of the pelvis follows a CT of the abdomen, the work effort for the technologist is not reduced. It takes just as much time to scan two separate areas (pelvis and abdomen) on one patient having both areas as it does for two patients each area. The question becomes of the total work time how much do each of the components contribute the overall practice expense (PE) for the technical component of these radiology services and does it vary across families of codes.

For example, in ultrasound we find that in some situations clinical labor activities do require duplication of work depending upon the scenario. We would like to comment on each of the above clinical labor activities and why we feel Medicare's assumptions are incorrect.

1. Greeting the patient: There are situations where two different sonographers may greet the patient. With the current national shortage of sonographers this may be more common than believed. Scenario: A male sonographer takes the next patient to be scanned. The patient is a female. The exams ordered are a pelvis complete or limited and a transvaginal ultrasound. The male sonographer completes the trans abdominal pelvis ultrasound and asks a female sonographer to complete the transvaginal exam. In this case two different sonographers would greet the patient.

2. Positioning and escorting the patient: nearly every combination of exams listed in Family 1 results in repositioning the patient and/or the table. Scenario: The primary care physician orders an ultrasound of the pelvis and a transvaginal ultrasound. The pelvis ultrasound is performed in the supine position. Performing the transvaginal ultrasound requires getting the patient up, reconfiguring the table and using stirrups.

3. Providing education and obtaining consent: We agree that obtaining consent is not duplicated for subsequent imaging when performing multiple procedures. However, prior to and during each separate exam, the sonographer provides a full explanation (education) of the procedure to the patient.

4. Retrieving prior exams: We agree that retrieving of prior exams for multiple procedures requires very little or no additional clinical labor activity. However, we would like to point out that each prior exam must be thoroughly reviewed by the sonographer resulting in additional clinical labor activity. This review includes images from other modalities, which further compounds the amount of activity necessary when multiple procedures are performed.

5. Preparing and cleaning the room: Again, we disagree with Medicare's statement that this activity is not duplicated with multiple procedures. Any procedure performed in combination with a transvaginal ultrasound requires the following:
    a. additional table preparation for the transvaginal exam (e.g. stirrups);
    b. the sonographer leaves the room to retrieve a transvaginal probe. Transvaginal probes must be disinfected and JCAHO policy dictates that probes disinfected with Cidex must be stored outside the exam room.

Also, scanning time for multiple ultrasound exams performed on contiguous body parts is equal to the same exams performed in a single session. Furthermore, we believe that scanning time makes up the vast majority of the clinical labor activities of ultrasound procedures. This could vary depending on the family of codes. For example, CT scans and ultrasound scans and MRI or MRA scans might vary considerably affecting cost in each of these component parts. It is for this reason that we strongly oppose an across the board reduction of 50 percent for these services.

Lastly, CMS has also listed codes within families that are already edited for unbundling. For example, if you perform a CT w/o dye and then perform a CT with dye, it should be billed under the code for CT w/o and w/ dye as recommended by AMA CPT coding. It is a misconception that these would be billed separately because Medicare already requires that the two codes be bundled into the most expensive code under the CCI edits.

APC 0112 – Apheresis, Photopheresis, and Plasmapheresis

We are concerned with the proposed 28.5 percent payment reduction for CPT codes 36516 – apheresis, selective and 36522 - photopheresis, both of which are in APC 0112. The proposed 2006 reimbursement for these procedures is $1,590.08, relative value of 26.6734, which is significantly lower than the current payment of $2,127.26 and relative value of 37.3315.

The proposed payment rate for CPT 36516, LDL apheresis, is less than 50 percent of the current costs for the procedure including supplies, indirect costs, cost of capital, and allied health effort. The current payment level likewise does not support the cost of providing this service for Medicare beneficiaries. Further reduction of the payment will result in a significant financial loss per procedure and will result in few institutions providing these lifesaving treatments. This will adversely affect access for and the health of patients requiring these procedures.

Likewise, the current costs for photopheresis at our institution including supplies, indirect costs, cost of capital, and allied health effort is equivalent to current payment levels. The proposed reimbursement is well below these costs and may result in institutions no longer providing these treatments for Medicare beneficiaries.

We request that CMS reconsider their proposed payment rate for this APC. CMS needs to base the proposed fee structure on more realistic costs per procedure and consider grouping the procedures in the separate APCs. We would be happy to share cost data with CMS concerning these two procedures and/or recommend CMS work with the American Society for Apheresis to obtain more accurate cost information.

Rural Hospital Adjustment

The commenter respectfully requests that the Secretary complete an analysis to determine if Medicare Dependent Hospitals' (MDHs) outpatient costs are higher than urban hospitals outpatient costs, and provide an adjustment to payments if appropriate.

For purposes of this analysis, MDHs are an important subgroup of rural hospitals because of their dependency on adequate Medicare payments. CMS already provides relief to Critical Access Hospitals by basing outpatient reimbursement on costs, and is proposing to adjust Sole Community Hospitals payments based on this analysis. An analysis of costs of the other rural hospital designation would determine if a payment adjustment is necessary to reflect the higher costs on the large percentage of the MDHs' patient population.

Section 1833(t)(13)(A) provided broad discretion to the Secretary to complete an analysis determining if rural hospital outpatient costs exceed urban outpatient costs, and to provide an adjustment to reflect the potential higher costs. This broad discretion provides the Secretary the authority to expand the analysis to determine if Medicare Dependent Hospitals also incur higher costs, and to provide an adjustment if necessary.

DRG Administration

There appears to be a clerical error on page 42739 (middle column). The second paragraph should read "... administration using codes 90471 or 90472 ..." The codes were erroneously listed at 96471 and 96472.

Thank you for the opportunity to comment. We sincerely appreciate your consideration of these comments. Please contact either Rob Kelly at (480) 301-4090 or me at (507) 284-4627 if you have any questions.

Very truly yours,

Ronald Grousky
Director, Medicare Strategy Unit
Mayo Clinic

cc: D. Hertel

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Baystate
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VIA ELECTRONIC MAIL AND OVERNIGHT DELIVERY

September 14, 2005

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RE: CMS-1501-P: Proposed Changes to the Hospital Outpatient PPS

NOTE: "Partial Hospitalization" Comments

Dear Dr. McClellan:

As one of New England's largest health care systems, Baystate Health System appreciates the opportunity to provide comments on the "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" as published in the July 25, 2005 *Federal Register*.

We are providing comments that specifically pertain to the proposed partial hospitalization (PHP) and community mental health issues.

About Baystate Health System

Baystate Health System, based in Springfield, Massachusetts, is one of New England's largest health care systems with approximately 9,000 employees, and consists of three member hospitals – Baystate Medical Center in Springfield, Franklin Medical Center in Greenfield, and Mary Lane Hospital in Ware; as well as the Baystate Visiting Nurse Association & Hospice. In addition, the not-for-profit health system features a diverse array of physician practices and ancillary health care services serving communities throughout Western Massachusetts.

As the flagship hospital of Baystate Health System, Baystate Medical Center in Springfield, MA is the region's only tertiary care referral medical center and Level 1 Trauma Center, and is

accredited as "one of the highest-rated hospitals in the country" by the Joint Commission on Accreditation of Healthcare Organizations. The nearly 600-bed teaching hospital is the Western Campus of Tufts University School of Medicine, and serves as a regional resource for specialty medical care and research, while providing comprehensive primary medical services to the community.

Franklin Medical Center in Greenfield, MA, a member of Baystate Health System, provides high quality inpatient and outpatient services to communities in Franklin and Hampshire counties and Southern Vermont. The Birthplace, Cardiopulmonary Services, outpatient surgical services, and the Medical/Behavioral Unit are some of the specialized programs available at Franklin Medical Center.

Partial Hospitalization (PHP) – specifically – has long been a level of psychiatric care offered by both Baystate Medical Center and Franklin Medical Center. Together, our BMC and FMC PHP programs serve annually over 500 individuals and provide over 4,600 patient care PHP visits. The Baystate Health System PHP programs are two of only *a small handful* of PHP programs in Western Massachusetts and serve a tremendous need for patients suffering from acute psychiatric and behavioral health disorders.

Franklin Medical Center's PHP is ***the only partial hospitalization program available to beneficiaries in Franklin County.*** As a rural community, Franklin County has a higher incidence of mental health issues serving a wide geographic area. As a community hospital, Franklin Medical Center is already "distressed" having received supplemental state funding in recognition of this and has already pared down its behavioral health services.

Both the BMC and FMC partial hospital programs offer much needed mental health services to individuals in a ***less restrictive*** and ***more cost effective treatment*** setting. Because our services are available, patients are admitted who require a "step down" from inpatient psychiatric care which results in shorter and more appropriate inpatients lengths of stay; or individuals can avoid a more costly and restrictive inpatient psychiatric admission because our program provides an appropriate "diversion" from this higher level of care.

Baystate Health System has serious concerns with Proposed Partial Hospital Changes.
We have serious concerns that the proposed changes to the outpatient prospective payment system (PPS) will have a negative affect on our partial hospitalization programs and our ability to be able to provide this service. As a provider, we are committed to finding ways to ensure that our patients have access to this essential level of care, however, our resources are limited. In addition, partial hospitalization capacity in the region remains a concern. We are very concerned about the impact of these changes to other PHP's in the region. Many ***partial hospital programs have been closed*** over the years and our services along with only a handful of other PHP's remain.

The reimbursement for behavioral health services nationwide and in the Commonwealth of Massachusetts, in particular has dramatically declined in the past several years to the point where most providers of behavioral health services can barely cover their costs. In most cases, medical center-based behavioral health programs, such as Baystate's, consistently ***do not cover their***

costs. With this reduced, inadequate level of reimbursement, these services must be subsidized by other medical center operations or forced to close. With CMS' proposed changes in reimbursement for partial hospitalization, it is likely that even fewer partial hospital programs will be available to patients who require and truly deserve this less restrictive and valuable level of care.

Medicare patients represent approximately 20% of our BMC PHP patients but almost 32% of our patients at FMC. The projected annual financial impact of these changes on our Baystate programs could be ***as much as $54,000***: $16,000 for BMC and over $38,000 for FMC. This amount may not seem like a large loss, however, the BMC and FMC PHP programs just barely cover their direct costs but do not cover their total costs. A reduction in reimbursement will ensure that these programs can no longer cover even their direct costs. Overall, behavioral health services at Baystate Health System lose approximately ***seven million dollars ($7M)*** each year with BMC losing five million ($5M) and FMC losing over two million ($2M). Clearly, any reduction in reimbursement to any of our behavioral health programs – in this case partial hospitalization -- is untenable.

ISSUES OF CONCERN

Like our counterparts nationwide and in the Commonwealth, we have several areas of concern and respectfully request reconsideration by CMS of its intentions to implement these changes until further comments, analysis and thoughtful evaluation can be conducted:

- The current methodology for determining the PHP rate is in flux.
  We understand CMS considered various approaches in the 2006 proposed rule in dealing with the complexities of the historical cost data supplied by hospital and community mental health center (CMHC) providers of the partial hospitalization benefit. Hospital affiliated PHP's and community based providers are very different. We also understand that the range of data provided by the CMHC's throughout the last five years -- from a high of $1,037 per diem cost to a low of $143 per diem -- has made it difficult to determine actual costs.

  Given the medical and clinical intensity of the partial hospitalization, we do not understand how this benefit could possibly be provided for $143. This figure raises serious questions about the *accuracy* of the data reported on CMHC cost reports. PHPs are required by regulation to provide a program of active treatment which includes at least three individualized treatment sessions per day, in addition to appropriate individual therapy and treatment planning. This level of intensity closely mirrors the care provided in an inpatient treatment setting. If partial hospitalization did not exist, beneficiaries would be hospitalized.

  We understand that the rationale for the CMS proposed 15% rate reduction in the rate (from $289 to $242.65) states that CMS believes this will recognize the decrease in the median per diem costs in both the hospital and CMHC data and also reduce the risk of any adverse impact on access to these services that might result from a large single-year rate reduction. However, CMS further states that you will continue to work with CMHCs to improve their reporting so that payments can be calculated based on better empirical

data. If it is recognized that the CMHC's reporting process needs improvement, then we respectfully note that the rate reduction should be reevaluated until better data is indeed available.

- A 15 % decrease in the per diem rate will negatively impact not only our programs but most importantly PHP beneficiaries and is an untenable variance in the payment rate. A PPS system is not designed to endure significant adjustments every year based on historical costs. Changes of the magnitude of 15% undermine the basis of the system. Providers and payers alike need to be able to rely on a predictable methodology for determining payment that will allow the PHP benefit to be available to Medicare beneficiaries in a stable way. This methodology needs to be predicated on reliable data.

- The methodology for the proposed 2006 PHP reimbursement rate does not adequately account for all important variables. The volatility in the CMHC data continues to be inadequately explained. There are many administrative costs (transportation, food) that are not Medicare-reimbursable. But these costs are real costs to the provider and need to be considered as payers and providers analyze the fiscal realities of providing the benefit. There are also highly prescriptive administrative and regulatory responsibilities that providers must meet in order to offer the benefit and which also contribute significantly to costs. In the new era of Medicare *inpatient* psychiatric prospective payment, it will be even more important that there be a *viable* alternative to hospitalization. Partial hospitalization *is* that alternative.

RECOMMENDATIONS

We respect the thought and effort that has gone into the determination of the proposed reimbursement rate for partial hospitalization for calendar year 2006; however we respectfully request that the following recommendations, which are also being proposed by our colleagues in other programs, behavioral health and psychiatry alliances, and regional and national provider associations, be considered:

- **Allow the time and resources necessary to fully develop an adequate payment methodology, we propose that the 2006 PHP payment rate remain the same as the 2005 rate - - $281.33.**

- **Consider using inpatient costs per day as the basis for the PHP median cost per diem.**

- **Further develop a cost method that uses, as an example, a three-year rolling average of the CMHC PHP cost per diem.**

- **Review and consider revising the various forms and worksheets used by CMHC's to report data.** For example: **CMHC cost report form (CMS-2008), settlement worksheet D on the CMS-2088 and the CMHC Provider Statistical & Reimbursement Report** ("PS&R") Report Type: 76P.

In conclusion, on behalf of the beneficiaries we *all* serve, we urge you to *not* reduce the rates for Partial Hospital programs for 2006, and delay any consideration of a rate reduction until a more reliable reporting methodology is devised. We very much appreciate your consideration of our concerns and your willingness to review our comments and recommendations. Thank you.

Sincerely,

Benjamin Liptzin, MD
Chairman – Department of Psychiatry

Amanda Hopkins-Alexiadis
BHS Director of Behavioral Health
Neurosciences and Rehabilitation Services

CC:
Mark R. Tolosky, President and CEO – Baystate Health System
Trish Hannon, Senior Vice President – BHS; Chief Operating Officer - BMC
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Burley

September 13, 2005

Via Electronic and U.S. Mail

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Room 445–G, HHH Bldg
200 Independence Ave., SW
Washington, DC 20201

Re: Hospital Outpatient Prospective Payment System Proposed Rule (CMS-1501-P) Update for Calendar Year 2006

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2006 (CMS-1501-P, *Federal Register*, Vol. 70, No. 141, Monday, July 25, 2005, p. 42674). AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually.

AdvaMed appreciates the considerable effort you and your staff have put into the development of the hospital outpatient prospective payment system (OPPS). We also appreciate your release of the 2004 outpatient hospital claims database and willingness to work with us to preserve beneficiaries' access to the full range of treatment options in the outpatient setting. AdvaMed is committed to a system that ensures that relative weights and payment rates under OPPS include sufficient resources to account for the costs of the medical technologies associated with hospital outpatient procedures and to assure Medicare beneficiaries have access to these technologies in the outpatient setting.

We will comment on the following topics raised by the proposed 2006 OPPS Rule:

- Support for CMS's stated commitment to ensure Medicare beneficiaries have timely access to new technologies including the expansion of CMS's interpretation of the requirements for pass-through payment categories and CMS's willingness to create new pass-through categories.

- Request that CMS set the floor on the proposed payment rate reductions for CY 2006 at 100% of the 2005 payment rates plus the market basket update for device-related APCs (including those device-related APCs not set forth on Table 15).

- Recommendations relating to CMS's determination of device-related APCs.

- Recommendations to appropriately capture device and technology costs in APC rates through the use of device category "c-codes;" educate hospitals on billing and coding for devices and technology; incorporate external data in determining costs; use single and multiple procedure claims in rate-setting; use only correctly-coded claims in rate-setting; and evaluate median cost data based on a sampling of hospitals.

- Recommendations to address charge compression.

- Recommendations relating to the movement of procedures from New Technology APCs to Clinical APCs.

- Recommendations specific to certain APC rates, including: providing descriptions and explanations of all changes; status indicator change for CPT Code 76937; status indicator change and APC assignment for HCPCS Code 0069T; status indicator change and APC assignment for 0054T, 0055T, and 0056T; and calculation of blood and blood product-related procedure rates, especially low volume procedures.

- Recommendation to remove the proposed AMA CPT Code requirement for New Technology APC applications.

- Recommendations concerning multiple procedure discounts.

I. Access to New Technology and Pass-Through Device Categories

AdvaMed appreciates CMS's stated commitment in the proposed OPPS Rule for 2006 to ensure Medicare beneficiaries have timely access to new technologies. Towards that end, we commend CMS for soliciting comments on the criteria related to pass-

through eligibility and applaud CMS's recognition that a traditional definition of surgical incision limits access to innovative, less invasive technologies that can be inserted through an orifice. These technologies offer benefits for Medicare beneficiaries and avoidance of more invasive, costly surgery. We believe this change will allow access to innovative and less invasive technologies – especially in the areas of gynecologic, urologic, colorectal and gastro-intestinal procedures – that meet the other stringent requirements for pass-through payment.

By way of implementation, CMS proposes to modify its current interpretation of the regulations (set forth at 42 C.F.R. § 419.66(b)(3)) to consider devices pass-though eligible if inserted or implanted through a natural or surgically-created orifice within the scope of surgically implanted devices, as well as those that are inserted or implanted through a surgically created incision. While this interpretation resolves the need to establish the existence of a traditional surgical incision to insert/implant a device through an orifice, we suggest that regulatory language be modified to institutionalize this change. The current language reads:

> *Sec. 419.66 Transitional Pass-through Payments*
>
> *(b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.*

AdvaMed respectfully requests that the language in the regulations be changed as follows:

> *(b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is implanted or inserted, through a natural or surgically created orifice or through a surgically created incision, whether or not the device remains with the patient when the patient is released from the hospital.*

AdvaMed also support CMS's willingness to create new pass-through device categories where an existing or previously existing category descriptor does not appropriately describe the new type of device. As AdvaMed has noted in the past, Congress intended to provide access through transitional pass-through payments to new and beneficial implantable devices. We believe CMS has sufficient documentation on devices in expired categories to differentiate them from new devices, and authority to clarify the definitions of previous categories to distinguish them from appropriate new categories.

II. CMS Should Set the Floor on CY 2006 Rates at 100% of the CY 2005 Rates Plus the Market Basket Update for Device-Related APCs Subject to Proposed Payment Rate Reductions

We do appreciate the efforts that CMS has made and are encouraged to see that the proposed rates for some device-related APCs will increase. However, we believe that the proposed 85% floor on payment rate reductions results in too much of a decrease in value for those device-related APCs whose medians were adjusted. Many of the APCs that are subject to the adjustment to 85% of the medians used to calculate the proposed 2006 payments have experienced decreases in rates from prior years and even in 2005 are not receiving a reimbursement level that recognizes the full costs of the devices and other resources required to perform these procedures. Also, a number of device-related APCs have been underpaid from the start of the OPPS. We are concerned that the continued reductions proposed for CY 2006 will prevent many hospitals from covering their costs, translate into significant losses for those hospitals that perform more of these procedures, and lead to access problems for beneficiaries.

For the last two years, CMS has established a floor on payment rate reductions to ameliorate the payment reductions. However, these floors are not nearly adequate to counteract CMS's reliance on inadequate data. This will continue to be a significant problem that will be exacerbated by CMS's intention to discontinue use of a payment reduction floor for future year's payment rates. The table set forth below illustrates the significant payment reductions that have been imposed on several device-related procedures since 2002.

APC/Description	**2002**	**2003**	**2004**	**2005**	***2006***	***Change***
0039 – Implantation of Neurostimulator (Neurostimulator)	$15,489	$11,876 -23.3%	$12,832 8%	$12,532 -2.3%	*$10,765* *-14.1%*	*-30.8%*
0087 – Cardiac Electrophysiologic Recording/Mapping (3-D Recording and Mapping System)	$2,670	$2,504 -23%	$2,172 6%	$2,122 -2%	*$1,822* *-14.1%*	*-31.7%*
0107 – Insertion of Cardioverter-Defibrillator (ICD pulse generator only)	$19,428	$17,013 -12.4%	$18,394 7.5%	$17,963 -2.3%	*$15,431* *-14.1%*	*-20.5%*
0108 – Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads and Pulse Generator (ICD system)	$29,360	$23,131 -21.2%	$24,700 6.4%	$24,121 -2.3%	*$20,721* *-14.1%*	*-29.4%*
0674 – Cryoablation of the Prostate (Probe, cryoablate)	$7250 - $7750 ($2750 + pass-thru of $4500-$5000)	$7781-$8281 ($3281 + pass-thru of $4500-$5000) 6.8%	$6545 -20.9%	$6392 -2.3%	*$5684* *-11.0%*	*-26.6%*

As such, AdvaMed urges CMS to set a floor on the 2006 device-related APC rates at no less than 100% of the 2005 rates plus the market basket update for all device-related

APCs. Although this will not alleviate the unsustainable reductions many devices have experienced over the past several years, it will provide a greater level of continuity.

III. Device-Related APCs

AdvaMed is also concerned about other device-related APCs that CMS did not include in Table 15. Many of these are proposed to receive significant reductions and do not benefit from the protection of the payment floor. For example, the APCs for brachytherapy procedures are all defined by the FDA to be device-related since they require a radioactive source, but they do not appear on Table 15 (APCs 312, 313 and 651). Of these, APC 651, Complex Interstitial Radiation Source Application, is scheduled to receive a 42.3% reduction in payment rate and is currently not eligible for the 85% floor because it is not included on Table 15.

APC 112, Apheresis, Photopheresis and Plasmapheresis, is another example of a device-related APC not listed on Table 15 that should be included as a device-related APC and subject to the payment reduction floor. APC 112 includes three HCPCS codes:

- 36522: Extracorporeal photopheresis;
- 36515: Therapeutic apheresis with extracorporeal immunoadsorption and plasma reinfusion; and
- 36516: Therapeutic apheresis with extracorporeal selective adsorption or selective filtration and plasma reinfusion.

All three procedures utilize device systems to modify or selectively remove agents from blood and return that blood to the patient. These device systems are major cost components and integral to the procedures. We believe the agency's proposed 25.25% reduction of the payment rate for APC 112 (from $2,127.26 to $1,590.08) is excessive and is likely to result in reduced access by patients to important therapy covered by this APC and undue pressure on providers who perform the procedure.

AdvaMed encourages CMS to include these and other similar APCs that will be identified by our members in the list of device-related APCs and where applicable apply the payment reduction floor to them. As noted above, we believe this floor should be set at 100% of the 2005 rates plus the market basket update for all device-related APCs. Again, although this will not alleviate the unsustainable reductions these device-related APCs have experienced, it will at least impose some limitation on the significant reduction in the payment rates from 2005 to 2006 and provide some stability.

IV. Continuing Insufficiencies in Claims Data and Appropriate Coding and Capturing of Device Costs and Charges for Device-Related APCs

A number of factors – the lack of hospital C-code reporting and hospital education on coding and billing, CMS's decision not to incorporate external data into its rate-setting

processes for 2006, CMS's heavy reliance on "single procedure" claims and insufficient data levels, CMS's decision not to use correctly coded claims, and CMS's omission of any discussion of charge compression – are all contributing to significant APC rate variations from year to year. Although CMS indicated in the proposed OPPS Rule for 2006 that the presence of C-code data in the CY 2005 claims will improve data for setting CY 2007 rates, AdvaMed believes that the irregular reporting of C-codes by hospitals is only one factor contributing towards the continuation of inaccurate data on which CMS is setting payment rates. While AdvaMed recommends that CMS address the payment inadequacies for CY 2006 by setting a floor at 100% of the CY 2005 payment rates for all device-related APCs that would otherwise experience a payment decrease, AdvaMed strongly urges CMS to take into consideration the following methodologies to improve payment rate calculations as the OPPS payment structure continues to mature.

Please note, however, that AdvaMed members will be submitting comments about specific APCs and requesting that CMS apply a variety of methods to the rate-setting calculations, including some of those methods set forth below. Where our members provide more detailed information and recommendations to appropriately adjust APC payment rates to more adequately reflect the actual costs of a procedure and related device, we respectfully request that CMS seriously consider their comments. The application of some of these methodologies may result in the increase of the CY 2006 payment rate above the CY 2005 rate and in those instances, application of the payment reduction floor will not be necessary.

A. Mandatory C-Codes

AdvaMed continues to support the mandatory reporting of all C-codes and related incentives to encourage hospitals to be more vigilant in reporting the total charges of performing device-related services. However, we wish to make it clear that while we support mandatory reporting of all device category C-codes, we recognize that there may be some procedure codes for which edits should not be established. For example, certain procedure codes may or may not involve the use of a device. In those instances when a provider submits a claim for a completed procedure that did not involve a device, it clearly would be inappropriate to have an edit in place that would send the claim back to the provider for inclusion of a device category C-code.

Although edits may not be appropriate in all instances, CMS nonetheless must make it clear to providers that the absence of an edit does not relieve them of their responsibility to report the appropriate device category C-code whenever a procedure is performed that does involve the use of a device described by one of the device category C-codes. Toward this end, we urge CMS to strongly consider comments from AdvaMed member companies on the device edits posted on the CMS web site. We believe the October 2005 edits will help to differentiate procedures requiring C-codes versus those procedures that may not require that C-codes be reported to reflect devices.

Requiring that all C-codes be billed and returning improperly coded claims will encourage hospitals to be more vigilant in reporting the total charges for performing device-related services. As such, AdvaMed urges CMS to continue the mandatory reporting of C-codes until a better methodology for collecting device data is in place.

B. Educating Hospitals on Device and Technology Billing

We urge CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for devices and other technologies. In addition to using C-codes, hospitals should be educated on how to report charges for those devices and technologies utilized in the outpatient department that do not have a special C-code designation or special HCPCS coding. For example, there should be clear instructions for consistent utilization of revenue codes. Accurate reporting of device and technology charges will ensure that these items' charges are included in future year's rates for outpatient services.

C. Utilizing External Data

During its February meeting, the APC Advisory Panel recommended that CMS address the problem of missing device data by incorporating external data into median cost calculations. A number of AdvaMed member companies provided data to CMS earlier this year, in time to be incorporated into the proposed rates. However, these adjustments were not made. Furthermore, CMS did not indicate in the proposed OPPS Rule for 2006 that it would take external data into consideration as it did in the proposed OPPS Rule for 2005.

When the medians used to calculate future payments fall below the previous year's adjusted medians, or when stakeholders present external data in response to this year's proposed rule that demonstrate the insufficiency of the data used to calculate the proposed payments or the insufficiency of the proposed payment rate, AdvaMed recommends that CMS make adjustments that more accurately represent the cost of performing the device and technology-related services, including the incorporation of external data provided by manufacturers and other stakeholders into the median cost calculations.

For example, the proposed 2006 payment rate for APC 674, Cryoablation of the Prostate, is not sufficient to cover the cost of the procedure. In fact, there is a shortfall of approximately $3,000 between the documented hospital cost to provide the procedure and the 2006 proposed payment rate for APC 674. External data has been submitted to CMS for the past three years illustrating that it costs hospitals over $9,000 to provide cryosurgery of the prostate. There is a very real probability that patient access will be affected as evidenced by the 30 hospitals that have cancelled or elected not to initiate a cryosurgery of the prostate program because of low Medicare reimbursement.

Another example involves CPT 20982, Percutaneous Radiofrequency Ablation of Bone Tumor(s), including CT Guidance. This CPT Code was established in 2004 and assigned to New Technology APC 1557 with a payment rate of $1,850. At that point there

were no hospital claims data available to support the APC assignment and no explanation was given by CMS indicating what data was used to assign CPT 20982 to APC 1557. For 2006, CMS proposes to keep CPT 20982 in APC 1557 based on 16 single frequency claims available in the CMS data files for 2004. However, the 2006 Physician Fee Schedule CPEP/AMA survey indicates a total procedure cost of $2,914.78. This data demonstrates that personnel and supply costs exceed the assigned APC 1557 payment level without a capital equipment allocation.

Yet another example involves Endovenous Radiofrequency Ablation of Venous Reflux (RFA), which was assigned new CPT codes (36475 & 36476) effective January 2005. RFA also had a C-code in effect until the end of 2004. The decision was made to assign these codes to APC 92 based on clinical similarities within the APC (traditional vein stripping). Unfortunately, the other procedures assigned to APC 92 do not have significant disposables or equipment costs associated with the procedure. Most vein stripping cases have approximately $30 in disposable costs, whereas RFA has a $725 disposable catheter cost plus the costs of additional supplies and capital equipment required to perform the procedure. Thus, the $1538 APC 92 payment rate does not factor in the disposables costs that were previously accounted for via a C-code nor does the rate even closely approximate the total cost for RFA which is approximately $2800.

D. Reliance on Single and Multiple Procedure Claims

AdvaMed remains concerned with CMS's heavy reliance on single procedure claims and reluctance to factor in device-related procedures reported as part of multiple procedure claims resulting in an artificially limited data set. Significant reductions in CY 2006 payment rates for a number of device-related APCs are a direct result of the inaccurate capture of device costs estimated from CMS's single and "pseudo" single procedure claim rate-setting methodology. This is particularly problematic for procedures routinely performed in conjunction with other procedures (*e.g.*, add-on multi-vessel stent codes for intravascular ultrasound, radiation oncology, and brachytherapy) whose costs, by definition, would always be reported on multiple procedure claims, but under single claims methodology are not being captured. For example, CMS is relying on just 111 "single" claims out of a total of 7,041 (1.5%) to estimate median costs for APC 670, Intravascular and Intracardiac Ultrasound. Another example is APC 651, Complex Interstitial Radiation Source Application, where there were 11,963 claims that contained CPT code 77778, however, CMS based the 2006 proposed payment on just 342 claims or approximately 2.8% of the 2004 outpatient claims. As such, AdvaMed urges CMS to create APC payment rates using both single and multiple procedure claims.

E. Use of Correctly Coded Claims

Since the program's inception, CMS has utilized various steps to filter the outpatient hospital claims data, including methods to artificially generate additional "single service" claims. The result has been the capture of more claims, but not necessarily better data. In setting the 2003 and 2004 rates, CMS utilized a C-code screen

that selected correctly coded claims for calculating the medians of about 40 APCs, generally resulting in medians that more accurately reflected the hospitals' costs incurred in performing device-related procedures. We believe that this screening process is evidence that CMS can and should establish rates based on a subset of accurately coded claims.

For example, APC 651, Complex Interstitial Radiation Source Application, includes one CPT code 77778, Interstitial Radiation Source Application; Complex. This interstitial brachytherapy procedure is used to code for prostate brachytherapy, a high volume cancer therapy, as well as other complex interstitial brachytherapy procedures that utilize more than 10 brachytherapy sources per procedure. The 2006 proposed payment for APC 651 is $720.71, which is a 42.3% reduction in the current payment of $1,248.93. Based upon our analysis, it appears that CMS did not use "correctly coded" claims to set the 2006 proposed rates for CPT 77778. If CMS had used claims that contained CPT 77778 and at least one brachytherapy device C-code, the correct code screen yields only 181 claims but the median cost is increased by approximately 18% to $864.54.

Another example involves APC 313, High Dose Rate Brachytherapy. Our claims analysis indicates that approximately 60% of claims did not include the Iridium-192 source C1717 and yielded a median cost of $776.35. However, the 3,442 correctly coded HDR brachytherapy claims had a more accurate median cost of $849.39.

APC 87, Cardiac Electrophysiologic 3- Dimensional Recording/Mapping, is another example of the importance of using correctly coded claims. When the "correctly coded" proxy screen is applied and only claims containing packaged revenue center costs (*i.e.*, device costs) are employed for rate development, the median increases by 81%. This is very strong evidence that the median cost is not accurately represented in the CMS claims data used for rate development of APC 87.

In past years, CMS has used only "correctly coded" claims to determine payment rates. AdvaMed strongly recommends that CMS use only correctly coded claims for all device-related APCs including those that are not set forth on Table 15 in setting payment rates. Although the use of correctly coded claims will not resolve the effect of charge compression (addressed below in Section V), it will result in payment rates that more appropriately reflect the costs associated with these procedures.

F. Improving the Data Used in Calculating APC Median Costs by Developing a Sampling of Hospital Claims Data

AdvaMed recommends that, in consultation with hospitals, manufacturers, and other stakeholders, CMS should consider approaches to collecting, analyzing and utilizing more detailed and accurate cost data from a nationally representative sample of hospitals. Such a sample could be used to validate findings from the larger claims data set and/or to establish median costs that more accurately reflect the costs of providing device-related

procedures and other outpatient services.

One alternative approach would be to conduct a demonstration project that would develop a sample of hospitals (for example, 100-300 hospitals), receiving small grants for set-up and training, to test the feasibility of collecting a valid, reliable and manageable data set from which to develop payment rates.

V. Charge Compression

Under OPPS, payment rates for device-related procedures are based on cost data generated by CMS's cost finding principles. Generally, CMS multiplies charges by hospital-specific cost-to-charge ratios (CCRs) to calculate hospitals' costs for all services in a single revenue center, reducing the charges by a constant factor. This methodology is based on the assumption that each hospital marks up its costs by a uniform percentage within each department to set each service's charge. However, a recent AdvaMed study (previously provided to CMS and attached to this letter for reference) found that hospitals typically have a smaller mark-up for higher-cost devices compared to other items and service. MedPAC's 2003 survey of hospital charge setting practices confirmed that hospitals often use smaller mark-ups on more expensive items. In practice, CMS's methodology does not recognize hospitals' variability in setting charges. If CMS uses a single CCR to estimate costs, the approach will generally lead to an underestimation of hospitals' costs for higher cost items – a phenomenon referred to as "charge compression."

The table[1] below illustrates the variation in mark-up in charges for certain implantable devices in a single revenue center. The mark-up for ICD pulse generators is 79% lower than for other less costly devices, leading to charge compression.

Device Type (from least to highest cost)	Sample Size	Percentage Mark-Up (Mean)
Pacemaker Lead	111	266
ICD Lead	69	221
Pacemaker Pulse Generator	111	221
ICD Pulse Generator	60	142

To the extent that hospitals' mark-up for high cost devices are systematically out of line with the hospitals' mark-up for other items and services, the payment levels for APCs corresponding to these devices are likely to be underweighted and underpaid. The effect on the APC may be especially pronounced when the charge for the device accounts for a high percentage of the total charges associated with an APC, as it would for many

[1] Premier Healthcare Informatics, Perspective Comparative Database for January 1 through December 31, 2004.

implantable devices with high unit costs.

We realize that an issue as complex as charge compression will require coordination and communication between the device industry, hospital industry, and CMS. As such, we recommend that CMS convene a working meeting of representatives from device manufacturers, the major hospital associations, and hospital billing experts to develop proposals to address these issues. We would be happy to assist in the planning of such a working meeting, however, we strongly believe that resolving an issue as complex as charge compression will require CMS leadership and initiative. Not only will addressing these issues improve patient access to life-saving treatments, it will also improve CMS's ability to capture accurate cost data that will result in more appropriate payment rates.

In addition, we offer the following alternative mechanisms that CMS might consider to address the impact of charge compression on payment rates. Although none of these are new, and in fact, AdvaMed and its members have presented them to CMS through the course of various meetings in the last several years, we continue to believe that each of them has the potential to alleviate the problems associated with charge compression. These alternatives involve changing hospital cost accounting systems to separate out high-cost devices, or comparing CMS "cost" estimates off the claims to external data on costs and developing a correction factor to adjust the CMS CCRs for application to high-cost devices. Please note that these proposed alternative mechanisms were also set forth in a letter to Herb Kuhn, Director, Center for Medicare Management, dated September 13, 2005, pursuant to his request.

A. Establish a New Cost Center Solely for High-Cost Devices and Calculate the Appropriate CCR

Using this mechanism, the lower mark-up on high-cost devices will (eventually) become evident via CMS hospital cost reports. Although the impact of this will take several years to come to fruition, long term it will allow CMS to calculate and apply a more appropriate CCR to the high-cost devices resulting in payment rates that more accurately reflect the costs of these devices.

B. Conduct a Study to Determine a Correction to the CMS CCR for High-Cost Devices

If CMS is not willing to establish a new cost center as set forth above, perhaps a representative sample of hospitals would be willing keep their books with a sub-cost-center level for high-cost devices. CMS could then estimate a more appropriate CCR for high-cost and other devices based on the sub-cost-center level for these hospitals. For example, if the hospitals' accounting indicates a CCR average of .3 for low-cost devices and .6 for high-cost devices, and finds that share of device costs is 50/50, then the higher CCR should be used to calculate an adjustment for records for procedures that must use high-cost devices.

C. Incorporate External Data

As previously discussed in Section IV(C), CMS should always accept external data to validate its data and incorporate external data into its calculations in cases where there is insufficient claims data to set appropriate payment rates. This is especially important in cases where estimated acquisition costs substantially exceed estimated average cost from CMS data. CMS should adjust cost estimates based on this data on a case by case basis.

D. Calculate a Charge De-Compression Factor

Based on CMS data (obtained as set forth in paragraph B above or a similar manner) and external data, CMS could estimate the "mark-up function" from charges on claims and device acquisition cost data and incorporate this data into setting the CCRs – one for low-cost devices and one for high-cost devices. Applying a higher CCR to high-cost devices will result in a payment rate increase while at the same time applying a lower CCR to low-cost devices will likely result in payment decreases because the CCRs applied will more accurately reflect the actual costs of the devices.

VI. Moving Procedures from New Technology APCs to Clinical APCs (Other New Technology Services)

The proposed OPPS Rule for 2006 moves a number of device-related procedures from current New Technology APCs into clinical APCs (10 of which are highlighted in Table 11). AdvaMed continues to be concerned that half (5 out of 10) of the procedures in Table 11 will be moved to lower-paying APCs, many significantly lower compared to their 2005 rates. Our analysis of one of the affected APCs suggests that hospitals have only reported the device portion rather than the combination of device and procedure, which is critical if accurate rates are to be established when moving a procedure from a New Technology APC to a clinical APC. These inappropriate reductions will not only affect access to these new services, but could have a negative effect on other new technology in the pipeline. We recommend that CMS re-examine these procedures, and consider options that would prevent reductions in payment, including moving them into different APCs, utilizing external data for rate-setting purposes, and/or allowing them to continue in their current New Technology APC for another year. Furthermore, we urge CMS to apply the floor on the payment reduction that is applied to device-related APCs to procedures that are being transitioned from New Technology APCs to clinical APCs.

For example, CMS proposes to move HCPCS code C9713, Non-contact Laser Vaporization of Prostate, including Coagulation Control of Intraoperative and Post-operative Bleeding, from New Technology APC 1525 to the newly created APC 429, Level V Cystourethroscopy and other Genitourinary Procedures. This new technology service code was created in April 2004, meaning that CMS is basing its APC shift on less than nine months of claims data. While CMS has the authority to move new technology procedures out of New Technology APCs this quickly, it traditionally has allowed claims data from a longer period of time to be used before assigning new technology services to

clinically appropriate APCs. At the August 2005 APC Advisory Panel, a presentation was made on this issue by a device manufacturer, with several Panel members reporting that their hospitals were incorrectly coding these procedures. While the Panel ultimately agreed with CMS's proposal, the discussion raised serious questions about the accuracy of the claims data and the confusion among hospitals billing these procedures. If CMS finalizes this proposal, the payment rate for C9713 will fall by about 33%, from $3,750 to $2,511. AdvaMed is concerned this large cut may prompt patient access concerns. As such, AdvaMed urges CMS to keep HCPCS code C9713 in New Technology APC 1525 for at least one more year to allow for more claims data to be collected before assigning this procedure to a clinically appropriate APC.

VII. Other Device-Related APC Issues

A. Providing Descriptions and Explanations of All Changes

We note that some HCPCS codes were moved to different APCs without a discussion in the preamble providing a description and explanation for the changes. Also, the disposition of a number of Panel recommendations were not discussed. In the future, we urge CMS to include in the preamble a discussion of these changes to allow stakeholders to provide more constructive feedback during the comment period.

B. Status Indicator Change for CPT Code 76937

In the proposed OPPS Rule for 2006, CMS states that for 2006, CPT Code 76937, Ultrasonic Guidance for Vascular Access Requiring Ultrasound Evaluation of Potential Access Sites, Documentation of Selected Vessel Patency, Concurrent Realtime Ultrasound Visualization of Vascular Needle Entry, with Permanent Recording and Reporting, continues to be assigned a status-indicator of N, thus bundling the payment for this separate ultrasound study. This proposal is in direct conflict with a decision made by CMS in the 2003 Final OPPS Rule. In the 2003 Final Rule, CMS proposed to accept the recommendations of the APC Panel and provide separate payment in 2003 for all radiology guidance codes designated as "N" in 2002.

To ensure that Medicare beneficiaries have access to safe, high quality care, AdvaMed recommends that the Status Indicator assigned to CPT 76937 be changed to an "S" allowing for separate payment of this service when provided in the hospital outpatient setting and that CPT 76937 be assigned to APC 0268, Ultrasound Guidance Procedures, as the resources needed to perform CPT 76937 are comparable to the resources needed to perform CPT code 76946 or 76965, which are both cross-walked to APC 0268.

C. Status Indicator Change and APC Assignment for HCPCS 0069T

AdvaMed is concerned with the current outpatient reimbursement for the technical component of correlated audioelectric cardiography (HCPCS 0069T). In the 2005 Final Rule correlated audioelectric cardiography, described as "Accoustic Heart Sound

Services," was incorrectly assumed to add minimal additional cost above the cost of an ECG test (HCPCS 93005) which is performed at the same time. As a result, HCPCS 0069T, the technical component of the correlated audioelectric cardiography procedure, was assigned a status code of "N - Items and Services packaged into APC Rates" and was bundled into the payment for ECG (APC 99 with a proposed 2006 national payment of $22.58). In actuality, the cost to a hospital to perform correlated audioelectric cardiography is significantly greater than even the cost of performing the ECG itself. In order to quantify the cost differential, an AdvaMed member worked closely with several hospitals to calculate their cost to perform a correlated audioelectric cardiography test as compared to an ECG test. Based upon the analysis, it was determined that the cost for performing an ECG test is estimated to be $31.23. The analysis determined that a hospital's cost of performing a correlated audioelectric cardiography test is $54.95 which exceeds the cost for ECG by $23.72 per procedure.

Furthermore, we reviewed the median cost data used to establish the proposed 2006 APC payments (spreadsheet file "median_apc_1501p.xls" obtained from CMS website). The spreadsheet identifies the "True Median Cost" for APC 99 (the APC for ECG, HCPCS 93005) as $23.06. When we compared the estimated cost of a correlated audioelectric cardiography test, it exceeded the median cost by approximately 2.4 times. We also compared the cost of a correlated audioelectric cardiography test to the lowest median cost service within APC 99 (HCPCS code 93041 as defined in hcpcs_medians_1501p.xls obtained from CMS website) in accordance with section 1833(t)(2) of the Act and found that the cost of correlated audioelectric cardiography exceeded the "True Median Cost" of HCPCS 93041 by 4.09 times.

AdvaMed respectfully requests, that in order to establish equitable reimbursement for hospitals, that CMS modify the status code for 0069T from "N - Items and Services packaged into APC Rates" to status "S - Significant Procedure, Not Discounted when Multiple" to allow the HCPCS code to be mapped directly to APC 99. In doing so, hospitals would be able to receive a separate APC payment for the performance of a correlated audioelectric cardiography procedure.

D. Status Indicator Change and APC Assignment for 0054T, 0055T, and 0056T Computer assisted Navigation for Orthopedic Procedures

AdvaMed is concerned that CMS has not established hospital outpatient reimbursement for computer assisted navigation for orthopedic procedures described by CPT codes 0054T, Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure, with Image-Guidance Based on Fluoroscopic Images; 0055T, Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure, with Image-Guidance Based on CT/MR images; and 0056T, Musculoskeletal Surgical Navigational Orthopedic Procedure, Imageless, by assigning these codes to the appropriate APC.

Computer assisted navigation procedures is a class of technologies currently recognized and paid using CPT Category I and Category III codes. The Category I code

includes brain and spine procedures and is described by CPT code 61795, Stereotactic Computer Assisted Volumetric (Navigational) Procedure, Intracranial, Extracranial, or Spinal. For 2004, CPT created Category III codes for a more accurate representation of orthopedic procedures. We think it's important to emphasize that the spinal computer assisted navigational procedures can be viewed as a subset of "computer assisted navigational orthopedic" procedures in that there is a common technological theme and comparable technological resources associated with the entire class of computer assisted procedures.

CMS has properly recognized and assigned CPT 61795 to APC 302 with a proposed payment of $272. Unfortunately, 0054T, 0055T, and 0056T have been overlooked. Accordingly, we request that CMS assign the "orthopedic" computer assisted procedures to the same APC as computer assisted spine procedures (*i.e.*, APC 302) or establish a new APC which would include all the computer assisted procedures.

E. Blood and Blood Products

AdvaMed companies produce a broad range of technologies for the collection, testing, safety assurance, processing, storage and transfusion of blood. Our member companies continue to be concerned that low payment amounts for blood products and services will challenge hospitals' abilities to assure the availability of safe blood products.

We commend CMS's acknowledgement of the need to protect beneficiaries' access to a safe blood supply and its effort to provide outpatient blood billing guidance through the issuance of Program Transmittal 496. Although we have been hearing questions from hospitals about the transmittal, we believe that such guidance is a significant step toward consolidating and clarifying the blood reimbursement scheme for hospitals.

Notwithstanding, we are concerned about the proposed reductions in certain blood and blood product APC rates for 2006. For example, CMS proposes to pay $161.71 for a unit of leukocyte reduced red blood cells (APC 0954). Last year, the blood collection community surveyed blood centers nationally and found that the median hospital acquisition cost for leukoreduced red blood cells in 2003 was $198. We are concerned that the proposed 2006 rate is inadequate because since 2003, with the introduction of additional blood safety measures, the cost of leukocyte reduced RBCs has steadily increased.

As such, we support the APC Panel recommendation that CMS should use the CY 2005 rates as the floor for blood and blood products and the higher of the 2004 median or 2005 payment rate to set the payment rate. We believe this recommendation is consistent with the comments articulated by the American Association of Blood Banks and the American Red Cross, which we also urge CMS to consider. We also recommend that CMS thoroughly review the comments of AdvaMed member companies, which offer further detail on the blood product and service payment issues raised by the proposed rule and provide a variety of options on how to address these issues.

VIII. Proposed AMA CPT Code Requirement (New Technology APCs)

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application (for either a Category I or III code) be filed with CMS as a part of the application for a New Technology APC, along with CPT's letter acknowledging or accepting the CPT code application.

AdvaMed is concerned that the AMA CPT Panel may not be an appropriate forum for a federally mandated decision, and may add undue delay to decisions, preventing rapid recognition of new technologies for Medicare beneficiaries. The AMA CPT Editorial Panel is a private organization that is not subject to procedural protections, necessary for public policy making. AMA meetings are closed to the public, the bases for decisions are not available to the public, and there are no voting representatives on the AMA CPT Panel from the medical technology industry and medical technology manufacturers. Furthermore, the AMA CPT Editorial Panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act. Thus, requiring the submission to the AMA CPT Panel risks the involvement of an organization that may not be accountable as are all other agencies that are responsible for federal public policy decisions. Even the requirement that AMA only acknowledge receipt of the application suggests that the AMA has some potential "veto" power over a decision that arises uniquely within CMS's authority. AdvaMed suggests that delegating even this modest function to the AMA may be an unlawful delegation of federal decision making to a private organization.

In addition, the requirement that a CPT application be filed will not provide CMS with input from the medical community unless CMS is proposing to wait until the AMA CPT Editorial Panel has made a coding determination and that determination has been made public. Filing an application neither requires nor guarantees a review by the medical community. As such, the CPT code application will not provide CMS with additional information on the technology being evaluated, beyond what is provided as part of the New Technology APC application process, because the applications are very similar. Moreover, because of the timing of the CPT process, it is not reasonable for CMS to wait until a CPT coding decision has been made public to decide whether to assign a New Technology APC.

Finally, AdvaMed is concerned with CMS's position that either a Category I CPT code or a Category III CPT code application will be acceptable prior to submitting a New Technology APC application. This position fails to take into consideration the significant differences between these two types of codes. Category I codes are typically assigned to a procedure that has become an accepted standard of care thus defeating the purpose of adoption of new technology. If manufacturers are forced to apply for a CPT code before sufficient information is available, it is likely that the CPT Panel would assign a Category III "emerging technology" code that often results in a non-coverage decision by local

Medicare carriers and fiscal intermediaries, as well as commercial payers. Because of the risk of non-coverage associated with Category III CPT codes, manufacturers will be more hesitant to apply for a New Technology APC and a CPT code simultaneously. This will directly result in the use of more miscellaneous codes, decreased ability by CMS to track the use and cost of devices, and ultimately jeopardize beneficiary access.

For each of the reasons set forth above, AdvaMed strongly recommends that CMS not include this proposal in the 2006 Final Rule.

IX. Multiple Procedures

A. Device-Related APCs

When APCs are denoted as having a multiple procedures discount, the hospital receives the full payment for the most expensive procedure and half of the payment for each additional procedure. The discounts are intended to reduce hospital payments to account for efficiencies in staffing, scheduling, procedure room preparation, inter-operative, and other resources. AdvaMed is concerned that the multiple procedure discount is not being utilized properly with respect to device-dependent APCs. For these procedures, where the majority of costs are related to the purchase of the device, performing multiple procedures does not reduce the cost of the devices involved. By inappropriately applying the multiple procedure discount to device-dependent APCs, CMS creates inappropriate financial incentives that penalize hospitals for efficiently providing these services on the same day. We request that CMS assign a status indicator of "S" to device-dependent APCs because the rationale for multiple procedure discounting is not applicable and the use of discounting could serve as a disincentive to efficiently perform multiple device related procedures on the same day.

B. Multiple Diagnostic Imaging Procedures

Currently under OPPS, hospitals receive the full APC payment for each diagnostic imaging procedure for each service on a claim, regardless of how many procedures are performed using a single modality and whether or not contiguous areas of the body are reviewed. CMS proposes that whenever two or more procedures in the same family are performed in the same session, the first procedure will be paid at the full reimbursement level and the second at a discount of 50%.

AdvaMed agrees with the CMS position that, when some of the procedures identified by CMS are performed in the same session, some of the resource costs are not incurred twice. CMS utilized the Medicare Physician Fee Schedule methodology and data, rather than that of the OPPS process in developing this policy. Further, we believe that the hospital's CCRs and related cost-reporting methodology already take into account reductions for multiple imaging procedures. Since the OPPS methodology already accounts for the cost efficiencies of multiple procedures in the same session, an additional 50% reduction, as described in the proposed rule, would contradict this methodology and

systematically disadvantage hospitals relative to other imaging facilities. As such, AdvaMed supports the APC Advisory Panel's recommendation that CMS delay implementation of the multiple diagnostic imaging procedure reduction for one year until further study can be done to analyze the impact of this proposal.

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AdvaMed urges CMS to carefully consider the comments submitted by our member companies, as they provide a unique source of information in developing appropriate OPPS payment rates. We appreciate this opportunity to submit comments on the July 25, 2005 proposed OPPS Rule for 2006, and look forward to working with CMS to address our concerns.

Sincerely,

David Nexon
Senior Executive Vice President

cc: Herb Kuhn
Liz Richter
James Hart
Joan Sanow

Heart Rhythm Society℠

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APC/D-D

Kane
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Sanow
Bazell
Heygster

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Dear Dr. McClellan:

Re: Medicare proposed device reimbursement in hospital outpatient payments for 2006.

The Heart Rhythm Society (HRS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule on the Medicare Hospital Outpatient Prospective Payment System (OPPS) for FY 2006, published in the July 25 , 2005 *Federal Register* (CMS-1501-P). The Heart Rhythm Society is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients and the primary information resource on heart rhythm disorders.

"Device Related APCs"

The Heart Rhythm Society is very concerned with the proposed reductions for device related procedures, specifically for implantable cardioverter defibrillators (ICDs). The Heart Rhythm Society believes it is a requirement of any payment system to appropriately pay for medical services so as not to limit access to care or diminish the quality of care. The proposed reductions for ICDs are based on inaccurate and incomplete data. CMS acknowledged at the meeting of the Advisory Panel on APC Groups held August 17, 18, 2005 that the data used as a basis for this proposed rule "may not be accurate or complete".

The 2006 OPPS proposed rule payment rates for ambulatory payment classification (APC) groups 0107 Implantation of Cardioverter-Defibrillator and 0108 Insertion/Replacement/Repair of Cardioverter Defibrillator Leads and Insertion of Cardioverter-Defibrillator, mark the second consecutive year of payment decreases amounting to -16.8%. The proposed rates will not cover the hospital's cost of the ICD and additional procedural costs.

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ICDs have been shown in many clinical trials to save lives and reduce the enormous loss of life due to sudden cardiac arrest. The impact of a payment decrease of this magnitude will affect patient access to care. Given this unprecedented payment reduction, there will likely be no expansion of the availability of this life-saving clinical technology, as hospitals will not be able to absorb the losses associated with the implementation of a device implant program. As such, access to life-saving implantable defibrillation technology will become limited.

Recommendation

The CMS Advisory Panel recommended CMS create adequate payment levels for ICD procedures by using 100% of the 2005 payment rates plus the hospital update of 3.2% to create the 2006 final OPPS payment rates for APCs 0107 and 0108. The Heart Rhythm Society fully supports this recommendation and strongly encourages CMS to implement the 2006 final OPPS with this recommendation. If CMS staff have questions please feel free to contact Brian Outland, Manager of Regulatory and Reimbursement Affairs at boutland@HRSonline.org or 202-464-3433.

Sincerely,

Anne B. Curtis, MD

Anne B. Curtis, MD
President, Heart Rhythm Society

Mark D Carlson

Mark D. Carlson, MD
Chair – Health Policy Committee

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CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

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Henry H. Kramer, Ph.D., FACNP
Executive Director

SCOD

September 15, 2005

Kane
Sanaee
Hart
Bazell
Ahmed

Via UPS

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1501-P Comments on Proposed HOPPS Rule – Radiopharmaceuticals

Dear Dr. McClellan:

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) is pleased to submit these comments on the July 25, 2005 proposed rule on the Medicare hospital outpatient prospective payment system (HOPPS). CORAR has worked closely with CMS since the inception of HOPPS, and most recently met with Jim Hart, Don Thompson and CMS HOPPS staff on August 4, 2005, to assist in developing policies on Medicare payment for radiopharmaceuticals that support high quality care for Medicare patients. The July 25, 2005 proposal on radiopharmaceuticals presents very significant changes in Medicare payment methodologies for 2006, 2007 and beyond. Our comments offer recommendations to make these changes workable, appropriate, and consistent with the Medicare statute.

CORAR's comments are summarized below:

Payment for Radiopharmaceuticals in 2006 – Cost-to-charge ratios

- CORAR supports the interim use of Cost-to-charge ratio (CCR) methodology in 2006 but urges CMS to implement certain refinements:

  a. CMS should authorize the uniform use of hospitals' overall CCR, not department specific CCR. The resultant payment should not represent a significant reduction from 2005 HOPPS payment rates for that product;

b. CMS should create G codes specific for radiopharmaceutical handling costs; and

c. CMS should use the new G codes to pay an additional amount to reflect the higher handling costs for radiopharmaceuticals.

Payment for Radiopharmaceuticals in 2007

- There is no standard or uniform manufacturer-reported radiopharmaceutical ASP for the end product, typically defined by a HCPCS code as a unit dose, millicurie or microcurie. Manufacturers of radiopharmaceuticals sell components or kits to radiopharmacies and/or hospitals. Manufacturers generally do not have access to prices for the end product/unit dose, as is the case for conventional drugs.

- In addition to significant practical barriers, there are legal constraints that preclude the use of ASP for radiopharmaceuticals.

- Rather than attempt to determine average sales price (ASP) for radiopharmaceuticals based on some manipulation of a hypothetical radiopharmaceutical ASP, CMS should consider continuation of CCR methodology using general hospital CCRs, with adjustments for handling/overhead costs in 2007 and possibly beyond.

- Not only is ASP impractical, but it would impose a third and different payment method for radiopharmaceuticals in three years and would create significant disruption for hospitals.

- CORAR welcomes the opportunity to continue working with CMS to assess which methodology best determines the hospital average acquisition cost or average price, and can best meet hospital and Medicare patient needs.

A. Payment Methodologies for Radiopharmaceuticals in 2006 - CCR

CMS proposes a temporary one year policy to pay for radiopharmaceuticals in 2006 based on the hospital's charges adjusted to cost. CMS' intent is to maintain consistency whenever possible between the Medicare payment rates for radiopharmaceuticals from CY 2005 to CY 2006. CMS expressed concern about using the congressionally mandated GAO survey and study since the GAO reported purchase prices were substantially lower than 2005 payment levels, and CMS does not want rapid reductions in payment to adversely affect Medicare beneficiary access to services utilizing radiopharmaceuticals. See discussion at 70 Fed. Reg. Page 42,727.

As another reason to use the charges adjusted to costs, CMS cites the MedPAC study which indicated that hospitals currently include the charge for pharmacy overhead

costs in their charge for the radiopharmaceutical. CMS believes that payment based on charges converted to cost would be the best available proxy for the average acquisition cost, along with the handling cost. Id.

CORAR agrees that cost-to-charge ratios could be workable, if the following priority problems are resolved:

1. Certain department specific cost-to-charge ratios will fail to convert charges to "average acquisition costs" and could result in significantly distorted and often inadequate payment.

2. Hospital charges, notwithstanding the MedPAC report, do not include handling and overhead costs.[1]

Other concerns with department specific cost-to-charge ratios include:

- Hospital charge data and hence payment have been distorted by changes in HCPCS code descriptors.

- Hospital charges also reflect special arrangements with private payers which may not be consistent with conventional Medicare CCR assumptions.

- Hospital charges for certain radiopharmaceuticals are subject to the problems of charge compression.

- Some radiopharmaceuticals, such as therapeutic radiopharmaceuticals, may be disproportionately disadvantaged under a department specific CCR.

CORAR recommends below several critically important refinements that would improve a CCR approach. These refinements are essential because exclusive reliance on charges and department specific cost-to-charge ratios, even for only 2006, would fail to pay hospitals appropriately.

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1 CORAR, along with the Nuclear Medicine APC Task Force, have objected to statements in the MedPAC report that hospital charges for radiopharmaceuticals include handling and overhead costs. Most hospitals, in fact, do not include such costs in charges. See attached letters from the Nuclear Medicine APC Task Force and CORAR to MedPAC.

Recommendations for CCR in 2006

1. Appropriate "hospital **general/overall**" cost-to-charge ratio

CMS (or Medicare fiscal intermediaries) should use the hospitals' **general** cost-to-charge ratio, and not a pharmacy, radiology or department specific CCR. Department specific CCRs generally fail to reflect the unique features of radiopharmaceuticals. Typically, hospital departmental CCRs that are in the range of 0.10- 0.30 would seriously fail to reflect hospital radiopharmaceutical costs. In contrast, hospitals' general cost-to-charge ratios in the range of 0.4 to 0.5, when applied to most charges for radiopharmaceuticals, represent a better proxy for hospital acquisition costs.

CMS may want to consider a national and unique cost-to-charge ratio for radiopharmaceuticals during CY 2006 which could more accurately account for radiopharmaceutical handling and overhead costs.

Establish a payment floor

CMS should consider establishing a payment floor during 2006, based on an appropriate percentage of the 2005 payment rate for specific radiopharmaceuticals. CMS expressed concern that use of GAO data would trigger significant payment reductions that could jeopardize patient access. CORAR urges that CMS consider a "buffering" screen or protection (similar to certain device-related APCs), so that even use of CCR will not inadvertently, and for some products, result in severe payment reductions. Further, CMS should advise hospitals that reported charges should be corrected or updated to ensure accuracy of data.

2. Creation of G codes for radiopharmaceutical handling costs

The MedPAC report identified seven categories of drugs, with distinct handling costs. Radiopharmaceuticals had the highest relative median costs of all drugs. CMS has proposed to create three drug handling cost C codes. None of these three C codes would apply to radiopharmaceuticals. The absence or exclusion of radiopharmaceuticals from these C codes creates a major risk that radiopharmaceuticals will be improperly paid, especially since radiopharmaceuticals have the highest handling costs of the drugs studied by MedPAC.

CORAR recommends the creation of five additional G codes[2] unique to radiopharmaceuticals if CMS moves forward with its proposal to implement drug handling codes:

GRPX1 Diagnostic radiopharmaceutical (not compounded by hospital) requiring special handling, protective shielding and monitoring;

GRPX2 Therapeutic radiopharmaceutical (not compounded by hospital) requiring special handling, protective shielding and monitoring;

GRPX3 Diagnostic radiopharmaceutical (compounded and requiring calculations performed correctly and then compounded correctly by hospital) requiring special handling, protective shielding and monitoring; and

GRPX4 Therapeutic radiopharmaceutical (compounded and requiring calculations performed correctly and then compounded correctly by hospital) requiring special handling, protective shielding and monitoring

GRPX5 Radiopharmaceutical handling costs for separately billed compounding fee for external radiopharmacy

CORAR recommends that all RPs be paid separately and with the potential for the hospital to bill one of the above G codes (in addition to the radiopharmaceutical product code) to facilitate appropriate data gathering, recognition, and payment of handling costs for all radiopharmaceuticals.

3. Payment for special radiopharmaceutical handling costs

CMS should pay hospitals, utilizing the above G codes, for the handling and overhead costs that are necessary for the safe and effective preparation and disposal of radioactive isotopes – radiopharmaceuticals. These payments should be in addition to payment for the particular radiopharmaceutical.

CMS would have to initiate an educational effort to communicate to hospitals well in advance of January 2006 the need to a) utilize the new G codes, b) adjust radiopharmaceutical charges during 2006 to accurately reflect any changes in HCPCS code descriptor, and the relevant hospital cost-to-charge ratio, appropriate for calculating radiopharmaceutical payment.

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2 CORAR recognizes that objections were raised at the August 2005 APC Advisory Panel meeting to creating 3 new drug "C" codes in 2006. CORAR believes that G codes, available to all insurers, will assist hospitals in more accurate, consistent, and efficient billing for radiopharmaceuticals.

CUTLASS CAPITAL, LLC

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NT/APCs

Kane
Sanow
Hart
Bazell
Hunter
Spolter
Hostetler

September 14, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Proposed Changes to the OPPS Payment System and 2006 Payment Rates

Issue: New Technology APC

Dear Dr. McClellan:

Cutlass Capital, LLC is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 Federal Register notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

We would like to thank CMS for the opportunity to make recommendations regarding the proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

New Technology APCs
CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

Cutlass Capital, LLC is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization, utilizing closed processes, that are not subject to procedural protections typically required for public policy. AMA

meetings are closed to the public and the bases for decisions are not available to the public, including hospitals and physicians. The AMA CPT Editorial Panel allows no participation or representation from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

Clearly, the requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions.

The requirement to submit New Technology APC applications together with CPT code applications presents an inherent conflict of purpose. By definition, category I CPT codes are assigned to procedures that have become an accepted standard of care and are in widespread use. This conflicts with and, in fact, defeats the purpose of creating a special coding vehicle (new technology APCs) to facilitate adoption and dissemination of new technology and the collection of clinical data. If manufacturers are forced to apply for a CPT code before widespread use or extensive information about the technology is available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code. This often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries and many commercial payers thus denying Medicare patients access to technology. The end result of the proposed rule would be a disincentive for manufacturers, particularly smaller ones, to innovate and market novel and beneficial medical technologies.

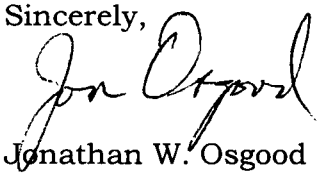
If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives from manufacturers on the decision making panel and offer additional concerned parties the opportunity to participate, comment, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiaries full access to the same high quality care in the hospital outpatient setting realized by patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

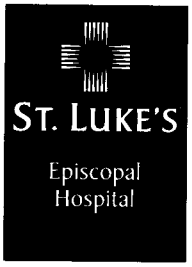
Should CMS staff have additional questions, please contact me.

Sincerely,



Jonathan W. Osgood
Managing Member

JWO:pd



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APC/D-D

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September 8, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare proposed device reimbursement in hospital outpatient payments for 2006

To Whom It May Concern:

St. Luke's Episcopal Hospital is a 946-bed acute care hospital located in the Texas Medical Center – Houston, Texas. As a major health care provider in our local area, we implant medical devices and perform other procedures on a number of Medicare beneficiaries in the outpatient setting. I am writing to express my concerns with the proposed rule, "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule," published in the Federal Register on July 25, 2005.

Implantable Cardioverter Defibrillators (ICDs)
In the proposed rule, the payment rates for procedures involving some devices were significantly decreased. As a health care provider of these services, these payment reductions are a serious concern. Changes should be made to the 2006 proposed payment rates for ICDs to be more closely aligned with the actual costs involved in providing these devices and services.

In the proposed rule, CMS recommends a decrease of 14.1% from last year's rate for ICD devices. Payment decreases of 14% from one year to the next are problematic and cannot be justified, particularly when the 2005 rates show a 2.3% reduction from the year before. No aspect of health care has dropped that much in two years. The resulting APC rates are lower than our institution's cost for the ICD device, leaving us with a loss for the device acquisition cost and no payment for our procedural costs. These losses make it very difficult for us to continue to offer device implant procedures in the outpatient hospital setting.

To rectify this issue, our facility requests that CMS calculate the 2006 payment rates for ICD implant procedures using 2005 payment rates plus the 3.2% hospital update. I understand that the August 2005 APC Advisory Panel has made the same recommendation to CMS. The resulting payment rates would be more in line with our facility's costs of performing these services.

Single Procedure Claims
In the proposed rule, CMS requested comments on the February 2005 APC Advisory Panel recommendation to increase the single bills available for rate setting to improve the accuracy of median costs for APCs 0107 and 0108. Although the scenarios displayed in the proposed rule may

increase the number of single bills used for rate setting, single procedure claims have not resulted in adequate payment since APCs were established. We are therefore unable to support the proposal.

Left Ventricular Leads

For 2006, CMS is proposing to move the left ventricular lead implant associated with cardiac resynchronization pacing and defibrillation systems (CPT 33225) from APC 1525 to APC 0418. Although the payment rate for the implant would increase from $3,750 to $6,458 with the proposed change in APC, the move to the new APC actually equates to a lower rate of reimbursement overall than the procedure was paid in 2005 ($3,229 v. $3,750) as the status indicator would change from a status "S" meaning that it was always paid at 100% of the APC payment rate, to a status "T" which means that it is subject to a 50% reduction in multiple procedure scenarios.

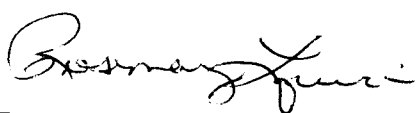
The assignment of status indicator "T" does not adequately compensate hospitals for additional procedural time and resources associated with this service. The implant procedure for the cardiac resynchronization pacing and defibrillator systems parallel that of a conventional dual chamber pacemaker or ICD with the exception of the implantation of a left ventricular lead and are therefore not duplicative.

Unlike conventional RA and RV leads the implant of a LV lead entails accessing an additional ventricle than that of a conventional pacemaker and defibrillator implantation; requiring transvenous placement in a cardiac vein via the coronary sinus. The additional approach to a coronary vein via the coronary sinus requires additional tools, mapping via venography and a different approach and technique to implant in a coronary vein and additional testing to assure appropriate capture.

The cost of the lead itself, which is the majority of the cost in the APC, is not reduced by 50% when implanted along with other procedures. Please do not change the status indicator for this procedure.

Thank you for this opportunity to provide comments on this very important payment update.

Sincerely,



Rosemary Luquire, PhD, RN, CNAA, FAAN
Senior Vice President, Patient Care &
Chief Quality Officer

We are well aware that MEG technology is not a panacea for diagnostic pre-epilepsy surgery evaluations, or for brain mapping in preparation for tumor or other lesion resection. On the contrary, there will be many cases where application of all known methods will not provide the desired answers. Unselective use of MEG would be unnecessary and inappropriate, but as physicians we are obligated both morally and professionally to provide our patients with the best available information and advice. At this point, this undoubtedly includes, where appropriately indicated, application of MEG methods.

MEG is an expensive technology. On top of the $2,000,000 to $3,000,000 initial cost of a system, construction of a magnetically shielded room costs about $400,000 to $500,000, the maintenance contract for the instrument is more than $100,000 a year, and liquid helium costs $30,000 to $50,000 a year. The cost of personnel adds significantly to these numbers. Additionally, the data analysis is frequently laborious and demanding. This is especially the case in MEG localization of epileptic foci (CPT #95965). Frequently analyzing a moderately complex epilepsy case takes much more time than analyzing multiple straightforward studies of evoked magnetic fields (95966 and/or 95967), which also require a significant amount of time. Taken together, these data argue for the necessity of maintaining the current level of reimbursement.

Inadequate reimbursement would severely affect the availability of, and access to, this already restricted but clinically very important technology. Professionally, it would represent a return to medicine of the 20th century, since its advantage over prior technologies is clear. We believe that American citizens and taxpayers do not deserve, and ultimately cannot afford anything but the best in the care of frequently disabling disorders of the brain. Thank you for your consideration.

Sincerely,

Steven T. DeKosky, M.D.

Mark L. Scheuer, M.D.
Associate Professor of Neurology
Director, Epilepsy Center, Adult

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